A Study of Two Models of Primary Mental Health Care Provisions in Yogyakarta, Indonesia



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SUMMARY

A study of two models of primary mental health care provisions in Yogyakarta, Indonesia

Background

The World Health Organization (WHO) defines health as a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. Despite its importance, mental health provisions are often limited. In 2015, Indonesia had only 773 psychiatrists for 250 million residents. This shortage of specialist mental health professionals is shared by most Low- and Middle-Income Countries (LMICs) and is reflected in the Treatment Gaps in this region indicating the very small proportion of people who receive adequate mental health care for their needs. While the median worldwide Treatment Gap for psychosis is 32.2% (Kohn et al., 2004), in Indonesia it is more than 90%. Experts suggested integrating mental health care into primary care, to help bridge this gap (Mendenhall et al., 2014). The systematic introduction of the World Health Organization Mental Health Gap Action Programme into primary care clinics across Indonesia and the presence of a 15-year-old co-location of Clinical Psychologists in Yogyakarta province's primary care clinics presented an opportunity to assess the clinical and cost-effectiveness of both frameworks.

Methods

This research ("the trial") set out to develop an approach, and then implement it, to compare the adapted WHO mhGAP framework with the existing specialist framework within primary mental health services in Yogyakarta, Indonesia, through a **pragmatic**, two-arm **cluster randomised controlled non-inferiority trial**. This design enabled an examination of patients derived from whole populations in a 'real world' setting. The trial involved two phases: a pilot study in June 2016 with the objectives to refine data collection procedures and to serve as a practice run for clinicians involved in the trial; as well as a substantive trial beginning in December 2016. The 12-item General Health Questionnaire (GHQ-12) was established as a 'fairly accurate' screening tool using a Receiver Operating Curve study. Using the GHQ scoring method of 0-0-1-1, a threshold of 1/2 was identified for use in clinical setting, i.e. the context of the trial. The primary outcome was the health and social functioning of participants as measured by the Health of the Nation Outcome Scale (**HoNOS**) and secondary outcomes were disability as measured by WHO Disability Assessment Schedule 2.0 (**WHODAS 2.0**), quality of life as measured by European Quality of Life Scale (**EQ-5D-3L**), and **cost of intervention** evaluated from a health services perspective, which aimed to determine the clinical effectiveness and cost-effectiveness of both frameworks at six months.

Results

During the recruitment period, 4944 adult primary care patients attended 27 participating primary care centres. Following screening (n=1484) and in-depth psychiatric interviews (n=394), 174 WHO mhGAP arm and 151 Specialist arm participants received a formal diagnosis and were recruited into the trial. The number of required participants per treatment arm, to provide statistical power of 0.80 and statistical

bilateral significance value of 0.05 was estimated to be 96. A total of 153 participants of the WHO mhGAP arm and 141 of the Specialist arm were followed-up at six months, representing 90.8% of all participants diagnosed. At follow-up, 82% (n=126) participants of the WHO mhGAP arm indicated they had attended at least one treatment session during the trial, significantly more than in the Specialist Arm (69%; n=97), $\chi^2 = 7.364$, p=0.007.

The WHO mhGAP arm was proven to be statistically not inferior to the Specialist arm in reducing symptoms of social and physical impairment, reducing disability, and improving health-related quality of life at six months. Cost-effectiveness analyses show that the Specialist arm was dominant for a unit of improvement in patient outcomes at six months. While the framework is more expensive for the Health System, participants in the Specialist arm were found to have larger improvements.

Conclusion

Given that both frameworks yielded positive patient outcomes, there is no immediate need to increase the absolute number of specialist mental health professionals in community psychiatry (i.e. replicate the specialist framework outside Yogyakarta). As most psychologists and psychiatrists in Indonesia reside in large cities, the current systematic roll-out of the adapted WHO mhGAP framework might address the need to strengthen non-stigmatising mental health care within community contexts, reflecting the preferences of primary care patients. In districts or provinces which could afford the additional cost, however, the Specialist framework was shown to be better at improving patient outcomes than the adapted WHO mhGAP framework. Existing resources for specialist care can be arranged in a hub-and-spoke (step-up care) model where higher-level interventions are provided for those with greater needs. The proposed model would free-up resources for advanced clinical training of the specialist workforce in key areas of need while keeping specialist services accessible.

Trial Registration

This trial has been registered with clinicaltrials.gov since 25 February 2016, NCT02700490.

Ehical Standards

Full ethics approval from the University of Cambridge, UK was received on 15 December 2015 (PRE.2015.108) and from Universitas Gadjah Mada, Indonesia on 14 April 2016 (1237/SD/PL.03.07/IV/2016). A condition of ethics approval from the University of Cambridge is that the investigator is covered by indemnity insurance and that participants are insured for the period of their participation. This was provided by the University of Cambridge Trial Insurance Office (609/M/C/1510). Ethics approval from all the clusters was not required as each cluster (*Puskesmas*) is a local GP surgery which does not have its own ethics committee. Instead, approval to conduct research at the province of Yogyakarta including all five districts: Kota Yogyakarta, Sleman, Gunung Kidul, Kulon Progo, Bantul Districts was obtained from the Provincial Government Office

(070/REG/V/625/5/2016) following ethics approvals. Written consent to participate was obtained from clinicians taking part as well as all patient-participants.

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LIST OF ABBREVIATIONS AND ACRONYMS

AUC	Area Under the Curve
BPJS	Badan Penyelenggara Jaminan Sosial (Social Insurance Administration Body)
CAT	UN Convention Against Torture
CI	Confidence Interval
CIS-R	Clinical Interview Schedule – Revised
CMHN	Community Mental Health Nursing
CONSORT	Consolidated Standards of Reporting Trials
CPD	Continuing Professional Development
CRPD	Convention on the Rights of Persons with Disability
CSRI	Client Service Receipt Inventory
DALY	Disability-Adjusted Life Years
EQ-5D	European Quality of Life – 5 Dimensions
GDP	Gross Domestic Product
HoNOS	Health of Nations Outcomes Scale
ICC	Inter-Cluster Correlation
ICCPR	International Covenant on Civil and Political Rights
ICD-10	International Classification of Diseases, 10 th Edition
ITT	Intention to Treat
KPSI	Schizophrenia Community of Indonesia
LMIC	Low and Middle-Income Country
MICE	Multiple Imputation by Chained Equations
NICE	The National Institute for Health and Care Excellence

NIHR	National Institute of Health Research
NPV	Negative Predictive Value
OECD	Organization for Economic Co-operation and Development
PPV	Positive Predictive Value
Puskesmas	Pusat Kesehatan Masyarakat (Community Health Centre)
RCT	Randomised Controlled Trial
ROC	Receiver Operating Curve
SD	Standard Deviation
SE	Standard Error
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
TG	Treatment Gap
TTO	Time Trade-Off
TTO UN	-
	Time Trade-Off
UN	Time Trade-Off United Nations
UN WHO	Time Trade-Off United Nations World Health Organization
UN WHO WHO mhGAP	Time Trade-Off United Nations World Health Organization World Health Organization Mental Health Gap Action Programme

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1 INTRODUCTION TO THE INDONESIAN MENTAL HEALTH LANDSCAPE: CHANGES AND CHALLENGES

Psychiatric disorders are increasingly considered to be killer diseases, reducing life expectancy. In highincome countries, this gap has been estimated to be from 8.0 to 14.6 life years in men and 9.8 to 17.5 life years lost in women, with a reported 20-year mortality gap for men and 15 years for women with psychiatric disorders compared to the general population. This mortality gap is attributed mainly to a combination of lifestyle risk factors, higher rates of unnatural deaths, and poorer physical health care (Thornicroft, 2011). This excess mortality is even higher in low- and middle-income countries (LMICs) (Fekadu et al., 2015). It is generally recognised that most people with psychiatric disorders in LMICs do not receive treatment based on the best current knowledge, if at all. Solutions to this problem, which may be tailored to various contexts, are necessary.

This Chapter begins by defining health, mental health and global mental health before explicitly reviewing the current Indonesian mental health system based on a thorough narrative review of the literature that was undertaken. Search terms included: "mental health system" AND "Indonesia". The originally planned systematic review did not successfully gather relevant grey literature and was subsequently abandoned in favour of a narrative approach, although relevant journal articles were retained and supplemented in this review by personal correspondence, online reports, and newspaper articles.

Within the investigation into the Indonesian mental health system and landscape, particular attention will be given to Human Rights violations towards people with mental health issues as well as the role that geography plays in strengthening primary care (and mental health within primary care) in the country. Subsequently, the topic of Treatment Gap is discussed, and the various proposed reasons why Treatment Gap remains enormous in Indonesia. Lastly, Indonesia's new Mental Health Law (2014) will be scrutinised and discussed. This chapter concludes with the proposed aims and objectives of the thesis, detailing research activities which were to be undertaken and the rationale behind them.

1.1 Global Mental Health

What is health? While the Oxford Dictionaries defines health as "the state of being free from illness or injury," the World Health Organization (WHO) defines health as a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. There are many critiques regarding this 1948 definition, deemed to have contributed to over-medicalisation of society and no longer relevant given the rise of chronic diseases, among others. Recent critiques include the absence of consideration towards spiritual health and environmental health. While those critiques are beyond the scope of this thesis to discuss, one should note that in many cultures and for many people, spiritual health is an integral part of wellbeing. For almost seven decades since the WHO definition, health has been acknowledged to have multiple domains, which contribute to the holistic wellbeing of an individual, community and society.

The three primary domains of health (physical, mental and social) are not equally regarded. Mental health is less understood (and often less valued), as the biological bases for many disorders remain and the interaction between mental health and environmental factors better understood. Mental disorders remain mysterious to many as is the realisation that mental health conditions can influence one's physical health (and vice versa), help-seeking behaviours, detection of physical health conditions, adherence to treatment, and overall prognosis (Prince et al., 2007). Both physical and mental health contribute to social health, which is the capacity to fulfil one's potential and obligations, the ability to manage one's life with a degree of independence, and the ability to participate in meaningful social activities, such as work (McDowell, 2006).

Mental health is "a state of well-being in which every individual realises his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community" (WHO, 2014). Psychiatric disorders have been found to be the leading cause of disability worldwide, with 28.5% years lost to disability (YLD), 2.3% years of life lost (YLL), and 10.4% of disability-adjusted life years (DALY) attributed to psychiatric and substance use disorders (Whiteford et al., 2015).

Psychiatric disorders reduce life expectancy by between 8.0 to 14.6 life years lost for men and 9.8 to 17.5 life years lost for women as described in a London study (Chang et al., 2011). Other studies have found a 20-year mortality gap for men and 15 years for women with psychiatric disorders, owing to a combination of lifestyle risk factors, higher rates of unnatural deaths, and poorer physical health care (Thornicroft, 2011). This mortality gap is even greater in low and middle-income countries (LMICs) (Fekadu et al., 2015).

Even more alarming, 800,000 people die through suicide each year worldwide (WHO, 2014). There are indications that for every successful suicide attempt, there are 20 unsuccessful attempts. Interestingly, 75% of global suicides occur in LMICs. Suicides, suicide attempts, and self-harm are often linked to

psychiatric disorders, pointing to the inability to cope with a given situation or realise one's potential. It has been estimated that 14.3% of premature deaths worldwide, or approximately 8 million deaths annually, are attributable to psychiatric disorders (Walker et al., 2015).

Discrepancies in health status between countries lead to the development of a new field within health research: global health. It is defined as "an area for study, research, and practice that places a priority on improving health and achieving equity in health for all people worldwide" (Koplan et al., 2009). Global mental health, in particular, is the application of these principles to the specific domain of mental, neurological, and substance use disorders (MNS) with the primary focus of reducing mental health inequalities within and between countries, particularly High-Income Countries vs LMICs (Patel and Prince, 2010).

There is indeed growing evidence for effective, locally feasible and affordable treatments for depression and schizophrenia in LMICs; the two conditions being the most commonly studied perhaps due to their relatively higher prevalence, compared to other conditions (Tiller, 2013). Systematic reviews have shown that non-specialist health worker interventions for mental health care in LMICs are clinically effective (Caulfield et al., 2018, van Ginneken et al., 2011). Other ways of managing mental disorders with less established efficacy information include traditional healers, religious exorcisms, and the removal of people with mental health issues from the community. Awareness of mental disorders, avenues to seek help, and the desire to get better, are all determinants of help-seeking efforts.

Often, mental health care is separate from physical health care. Compartmentalisation underestimates the overall burden of mental disorders, much of which is mediated through links with other conditions. It also misses the salience of mental health to mainstream health and human development. Separating mental health care from physical health care entrenches isolation and emboldens stigma towards those affected. Moreover, psychiatric disorders are linked to a cycle of disadvantage, including poverty, violence, and social exclusion (Lund et al., 2010). The social care systems of many countries perpetuate this inequity. While the impact of poverty alleviation on mental health is inconclusive, mental health interventions have been shown to improve economic outcomes (Lund et al., 2011).

In many LMICs, people with mental and psychosocial disorders continue to experience this wide range of human rights violations. These include stigma, social exclusion within families or communities, and discrimination in employment, education, housing, and broader society (WHO, 2001). Often, they are denied the opportunity to exercise legal capacity and civil, social, and political rights (Drew et al., 2011). People with severe mental health problems may experience the denial of basic entitlements, such as freedom of movement and the right to receive care (Patel et al., 2011). Abuse, inhumane and degrading treatment are commonplace, and these violations may happen in hospitals, private institutions, community facilities, or even at home (Drew et al., 2011). Discrimination, low social support, and negative self-image contribute to suicidality (Farrelly et al., 2015). Moreover, laws and

practices in many countries systematically deny people with mental disorders the right to exercise their legal capacity and make decisions, regardless of the severity of the disorders and usually without prior competency assessment. Instead, third parties such as health professionals, government officials, or family members make all decisions in their place, including decisions on treatment, living arrangement, as well as other personal, administrative and financial matters. These infringements of human rights have been referred to as a "failure of humanity" (Kleinman, 2009).

1.2 Indonesia State of Mind

Modern-day Indonesia is the largest economy in Southeast Asia. With a population of over 267 million in 2018, it is the world's fourth most populous country after China, India, and the United States (World Population Review). Geographically, Indonesia is an archipelago of 17,508 islands, 6,000 of which are inhabited. More than 700 languages are spoken in Indonesia, with the *lingua franca* being *Bahasa Indonesia* (CIA, 2015). While the majority (87%) of its population are Muslims, Indonesia is also home to Christians, Hindus, and Buddhists. Religious minorities are often targeted by militant Muslims in their campaign to Islamise Indonesia (Davis, 2002). During the global financial crisis, Indonesia outperformed its regional neighbours and joined China and India as the only G20 members posting growth. Despite this, around 11% of Indonesia's population lives below the poverty line (OECD, 2013). Indonesia still struggles with poverty and unemployment, inadequate infrastructure, corruption, a complex regulatory environment, and unequal resource distribution across regions. Health expenditures amounted to only 3.1% of GDP in 2013 (WHO, 2015), 1% of which was allocated to mental health care.

The health infrastructures and workforce are reflections of relatively small health expenditures. Ministry of Health data in 2015 recorded 2,447 hospitals exist in Indonesia, 17% of which are privately owned. These hospitals supply a total of 304,902 beds, a ratio of 1.22 beds per 1,000 population. The global average is three beds per 1,000, and the OECD average is five beds per 1,000. Indonesia has 0.4 medical doctors per 1,000 people, under a third of the global average of 1.4 doctors (OECD average is 3.2). There are five nurses per 1,000 population, 60% of whom are educated to high school level only (Hennessy et al., 2006). *Jamsostek*, the national insurance system which paid for basic healthcare before the implementation of Universal Health Coverage (BPJS) from 1 January 2014, covered approximately 60% of Indonesians. With BPJS, demand for medical care is predicted to increase steadily, placing a more significant strain on existing health infrastructures. The figure below illustrates the recorded use of BPJS between 2014-2016.

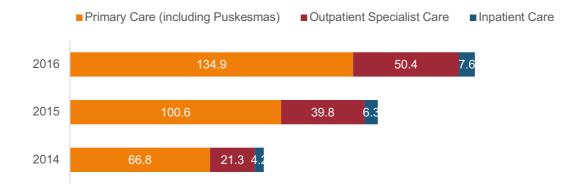


Figure 1. Increased demand for medical care between 2014-2016 (in millions), BPJS Data via Dr Maya Rusady, Director of Medical Services, 1 March 2017

Geography and health are intrinsically linked (Dummer, 2008) as reflected in the adjustment of the health system to consider population density, demographic profile, and accessibility. Approximately 57% of Indonesians live on the Island of Java, making it the most populous island in the whole world. Most (65%) medical doctors in Indonesia practice in Java. The island is home to ethnic Javanese (41.7% of Indonesia's population) and Sundanese (15.4%) although larger cities in Java, like Jakarta, are home to other ethnicities that have migrated. Indonesia has more than 300 distinct ethnic and linguistic groups, although the largest and most dominant politically are the Javanese. Ethnic Chinese Indonesians account for only 3% of the population but control most of the country's wealth and commerce, the by-product of the segregation of roles and living quarters during the 350-year Dutch colonial rule (Suryadinata, 1999). Presently, ethnic Chinese Indonesians continue to experience discrimination, ranging from the additional citizenship documents, limited quotas in state universities and civil service, as well as being the political scapegoat (Winarta, 2008). As economic growth in the country centres in Java, citizens living outside the island often complain about unequal access to development budget and infrastructures (Akita and Alisjahbana, 2002, Yusuf and Sumner, 2015).



Figure 2. Map of Indonesia and neighbouring countries (Source: Ezilon Maps)

It is more difficult to access health services outside Java as hospitals are few in number, despite broad geographical coverage (Shields and Hartati, 2003). On the other hand, it is not economically feasible to develop and maintain hospitals where population density is very low. The Indonesian government relies on community health centres or *Pusat Kesehatan Masyarakat (Puskesmas)*, to provide citizens with primary health services given the lack of feasibility to develop hospitals in areas with low population density (Mahendradhata et al., 2017). The majority (63%) of *Puskesmas* are outside Java. Recognising their role in filling the gaps in primary health services, many *Puskesmas* in Indonesia offer basic inpatient facilities. The healthcare system of the country, therefore, adapts to the geographical challenges. Table 1 details the number of government-owned, independent *Puskesmas* in the provinces.

NO	Province	PUSKESMAS (Community Health Centres)		
NO		Inpatient	Outpatient	TOTAL
1	ACEH	142	194	336
2	SUMATERA UTARA	164	406	570
3	SUMATERA BARAT	91	173	264
4	RIAU	79	132	211
5	JAMBI	68	108	176
6	SUMATERA SELATAN	95	226	321
7	BENGKULU	45	135	180
8	LAMPUNG	106	184	290
9	KEPULAUAN BANGKA BELITUNG	20	41	61
10	KEPULAUAN RIAU	28	44	72
11	DKI JAKARTA	30	310	340
12	JAWA BARAT	176	874	1,050
13	JAWA TENGAH	318	557	875
14	DIYOGYAKARTA	42	79	121
15	JAWA TIMUR	505	455	960
16	BANTEN	56	175	231
17	BALI	34	86	120
18	NUSA TENGGARA BARAT	109	49	158
19	NUSA TENGGARA TIMUR	134	236	370
20	KALIMANTAN BARAT	95	143	238
21	KALIMANTAN TENGAH	73	122	195
22	KALIMANTAN SELATAN	45	183	228
23	KALIMANTAN TIMUR	95	79	174
24	KALIMANTAN UTARA	32	16	48
25	SULAWESI UTARA	92	95	187
26	SULAWESI TENGAH	79	105	184
27	SULAWESI SELATAN	228	218	446
28	SULAWESI TENGGARA	86	183	269
29	GORONTALO	25	68	93
30	SULAWESI BARAT	44	50	94
31	MALUKU	62	135	197
32	MALUKU UTARA	27	100	127
33	PAPUA BARAT	40	109	149
34	PAPUA	104	290	394
TOTAL		3,369	6,360	9,729

Table 1. Number of *Puskesmas* in Indonesia, by Province (Shaded Provinces are in Java)

The Indonesian government has adopted the WHO definition of mental health. In 2013, the 15-year prevalence of depression and anxiety according to Basic Health Research was 6% (15 million people). Within-country surveys have revealed a significant cross-sectional association between depression and chronic heart disease, asthma, and arthritis (National Health Survey, 2009). Besides, the 15-year prevalence of severe psychosis is 0.17% (estimated number affected nearly half a million people, 425,000). Users of narcotic substances in the last year amounted to 2.2% of the population (4 million people), with a quarter of them being regular users (Badan Narkotika Nasional, 2001). In 2011, there were 1,170 recorded cases of suicide, or 0.5 per 100,000 people (National Police, 2012). Post-disaster prevalence of depression and anxiety is estimated to be 40% as assessed after the 2004 Boxing Day Tsunami and 2010 Mount Merapi Eruption (Irmansyah et al., 2010). While prevalence might seem lower than global averages, the enormous population of Indonesia, coupled with inadequate service infrastructure, impose a heavy burden on the mental health care system, judicial system, and the society in general. Furthermore, to date, there is no existing formal social care system.

Mental health services in Indonesia are arranged in primary, secondary, and tertiary levels of care. Since 2004 in Aceh, then in other parts of Indonesia, *Puskesmas* provide primary mental health care at the community level, including public education to individual patients, counselling, basic psychiatric services, house visits, community outreach, and referral to secondary care. This is in line with the task-shifting or task-sharing approach to primary mental health services recommended for low-resource settings (Barrett et al., 2009, Bruckner et al., 2011, Burns and Tomita, 2014, Mirza et al., 2006, Padmanathan and De Silva, 2013, Petersen et al., 2012, van Ginneken et al., 2011). In 2015, 30% of all *Puskesmas* in Indonesia (approximately 3,000) provided basic mental health services. Approximately 47% of *Puskesmas* have at least one staff member, usually a general practitioner or practice nurse, who has attended task-sharing mental health training, Community Mental Health Nursing (Rifaskes, 2011). Secondary care (outpatient psychiatric care) is available in less than half (41%) of general hospitals in the country. Patients are provided with emergency psychiatry, policlinic psychiatry (specialist outpatient), and liaison psychiatry (through A&E or hospital inpatient referral). At the tertiary level, psychiatric hospitals provide emergency psychiatry, inpatient facilities, and sub-specialist care. Not all provinces in Indonesia have a psychiatric hospital.

The World Psychiatric Association recently refocused efforts on attracting medical graduates to psychiatry training, as the number of medical doctors pursuing specialist training in psychiatry has declined markedly over the years resulting in a greater burden in the mental health care system both in developed countries and LMICs (Farooq et al., 2014). It has been noted that there is a 1.2 million mental health labour force shortage in LMICs and the scale-up costs are predicted to be around US\$840 million (Kakuma et al., 2011).

In 2015, Indonesia was home to only 773 psychiatrists for its 250 million residents (ratio of 0.32 psychiatrist for 100,000 residents or 0.1 per 30,000) (Nasional, 2016). A ratio of below one psychiatrist

per 30,000 indicates an insufficient supply of qualified mental health care professionals (Koran, 1979). In January 2019, the Indonesian Clinical Psychology Association recorded 980 verified members and approximated the presence of 1587 clinical psychologists in the country (anon., 2019).. Even prevalence using frequency of service contact is unlikely to be indicative of actual demand, yet there has not been a country-wide population-based study with reasonable response rates and rigorous methodology. Culture, stigma, geographical accessibility, and insurance status, among others, affect the utilisation of specialist services. Notably, Indonesia's Ministry of Health Director for Mental Health confirmed in a private conversation that most psychiatrists in Indonesia work in the private sector, except for a handful working in tertiary psychiatric facilities and psychiatrists in government hospitals. The fee-for-service healthcare system previously denied specialist psychiatric treatment opportunities for those without the means to afford private medical care. Similarly, few psychiatrists in other developed countries have been reported to accept state-insured patients (Bishop et al., 2014).

1.3 Abomination in Paradise

Many Indonesians with symptoms of mental illness are shackled in practice called *pasung* (Minas and Diatri, 2008). Their families often restrain people with mental illness due to their history of chronic or relapsing disease, lack of access to mental health services, family burden and/or financial issues, lack of response towards pharmacotherapy, and most importantly lack of knowledge and understanding of mental health (conference presentation at ASEAN mental health conference by, Diah Setia Utami, past Director of Mental Health Ministry of Health, Republic of Indonesia). Those in restraint are usually held in one place for many years (even up to their deaths). While some in *pasung* experience all-around neglect, most are chained nearby their relatives and continue to receive regular meals and family contact. Family members, therefore, believe that restraints protect their loved ones from trouble with the law, getting lost, or harming themselves. The Ministry of Health estimated around 57,000 Indonesians had previously been or are currently living under restraint in their lifetime (chain, wooden block, cage, among others). This phenomenon primarily appears in places with limited mental health resources and is seen as a breach of human rights (Freeman & Pathare, 2005). The Human Rights Watch published an online article on this phenomenon on 21 March 2016, titled "Living in Hell: Abuses Against People with Psychosocial Disabilities in Indonesia," https://www.hrw.org/report/2016/03/20/living-hell/abuses-against-people-psychosocial-disabilitiesindonesia.

For almost five decades, Indonesia has acknowledged the problem of *pasung* in its public policy. As early as the 1920s, nearly a hundred years ago and before independence, Dutch psychiatrists wrote extensively about the problem of *pasung*. In accordance with the 1966 law on mental health (Law No. 23, 1966), patients with mental disorders must receive care and treatment in healthcare facilities, and their human rights must be safeguarded. The Minister of Home Affairs Decree number PEM.29/6/15, dated 11 November 1977, addressed to the Governors of the Indonesian Provinces, stated that mentally

ill people must not be shackled or restrained and that there should be awareness raising programmes about mental health at all levels to be delivered by local governments. However, this policy was not enforced, and no effort was made to ensure compliance.

Subsequently, Indonesia has ratified international conventions such as the UN Convention Against Torture (CAT) in 1998, the Convention on the Elimination of Racial Discrimination (1999), and the International Covenant on Civil and Political Rights (ICCPR) in 2006, indicating intention to support human rights protection of those who are mentally ill within multi-ethnic Indonesia (Irmansyah et al., 2009a). Among over 300 recognised ethnic groups in Indonesia, ethnic Chinese has been targeted in several political uprisings, most notably in the May Riots of 1998, where they were blamed for the Asian Financial Crisis, resulting in the looting and burning of Chinese-owned businesses and homes, as well as torture and rape of Chinese women and girls (Kusno, 2003).

Furthermore, in 2010, the Indonesian Government, supported by Universitas Indonesia and the University of Melbourne, established its '*Free From Pasung*' programme, which includes human rights advocacy, public education of mental illness, and training of mental health professionals. Indonesia's Ministry of Health is committed to eliminating *pasung* practices by the end of 2019 (after moving the deadline twice from 2014 to 2017 and now to 2019). While this target is again likely to be delayed, the movement also indicates the level of commitment from academia, community organisations, volunteers, and local health authorities to promote mental health awareness and practices. Civil society organisations such as Schizophrenia Care Community of Indonesia (KPSI) and the Suryani Institute are working on raising awareness at the grassroots level in Java and Bali. Most recent data from 2013 estimates that around 18,800 Indonesians are in *pasung* and in 2015, 4,393 victims had been 'rescued' from this state (3,399 of them received psychiatric therapy). Professor Harry Minas from the University of Melbourne, a lead academic on the *Free From Pasung* programme, noted that in 2015, 20 out of 34 provinces in the country had adopted the *Free From Pasung* programme.

1.4 Treatment Gap

Low supply of mental health professionals and low demands for psychiatric services due to stigma, contribute to the wide Treatment Gap as illustrated in the figure below. While the median worldwide Treatment Gap for psychosis is 32.2% (Kohn et al., 2004), the Treatment Gap in Indonesia is estimated to be more than 90% (Ministry of Health data), reaching 96.5% in the village of Leuwiliang, West Java (WHO-SEARO, 2004). This enormous Treatment Gap means that only one in twenty patients with severe psychosis currently receives treatment. While this is in part due to the stigma of mental health issues, traditional beliefs often point to magic or demon possession as reasons for the alteration of a person's character or behaviour (Irmansyah et al., 2009b). Besides, commonly held beliefs that people with psychiatric disorders are incurable also led to the finality of their being locked up and hidden from

society. Relatively few Indonesians refer to psychiatric disorders as an illness with the potential for recovery.

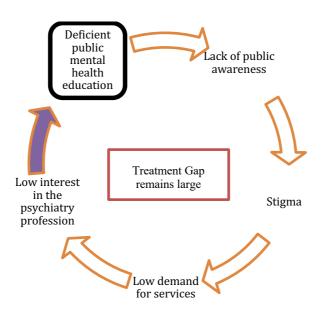


Figure 3. The Vicious Cycle of Indonesian Mental Health Service Utility

It is possible that the lack of public awareness of mental health issues actively fosters stigma towards mental illness. This stigma, in turn, is a barrier to help-seeking (Clement et al., 2015) resulting in low demand for psychiatric services. This low demand may in turn influence the number of medical professionals interested in psychiatry (supply creation/inhibition). As the number of psychiatrists in Indonesia remains small, Treatment Gap remains enormous. Psychiatrists in Indonesia are also expected to provide public mental health education. In a vicious cycle, the very small number of psychiatrists has contributed to low levels of public awareness, as illustrated in Figure 1. Increasing the number of psychiatrists is slow and costly. Going beyond this role for psychiatrists (shaded arrow in Figure 3) it is likely that a wider-reaching and more sustainable approach can and should be considered.

A comprehensive meta-analysis of randomised controlled trials looking at the effectiveness of stigma reduction programmes found that social distance interventions have small positive effects (Griffiths et al., 2014). Contact with persons with psychiatric disorders or educational interventions has been found helpful. For American adults, social contact is better than education at reducing stigma, and for adolescents, the opposite pattern was found (Corrigan et al., 2012). While Indonesian studies on stigma are limited, it is believed that a long-term approach to improving public awareness for mental health issues is through the education system. In addition, accounts from people with lived experiences can be compelling in challenging stigma (Yang et al., 2007).

1.5 Indonesia's New Mental Health Law

On 30 November 2011, Indonesia ratified the Convention on the Rights of Persons with Disabilities (CRPD). Against this backdrop, tackling human rights abuses of people with mental health problems has become an urgent policy priority. Increasingly, the provision of mental health care is being viewed as a fundamental human right. The World Health Organisation has made tackling human rights abuse a crucial part of their Mental Health Action Plan 2013–2020 (WHO, 2013). Considering widespread human rights violations and discrimination experienced by people with mental illness, the WHO argues that a human rights perspective is essential in responding to the global burden of mental disorders. The Mental Health Action Plan emphasises the need for mental health strategies, actions, and interventions for treatment, prevention and promotion to be compliant with the CRPD and other international and regional human rights instruments. The vision of the action plan is to create "a world in which mental health is valued, promoted and protected, mental disorders are prevented and persons affected by these disorders are able to exercise the full range of human rights and to access high quality, culturally-appropriate health and social care in a timely way to promote recovery, in order to attain the highest possible level of health and participate fully in society and at work, free from stigmatization and discrimination" (WHO, 2013).

Within this context, mental health service legislation in countries that have ratified the CRPD must consider these main themes: (1) the right to adequate standard of living (Article 28 of the CRPD); (2) the right to enjoy the highest attainable standard of physical and mental health (Article 25 of the CRPD); (3) the right to exercise legal capacity; (4) the right to personal liberty and the security of person (Articles 12 and 14 of the CRPD), freedom from torture or cruel, inhuman or degrading treatment or punishment and from exploitation, violence and abuse (Articles 15 and 16 of the CRPD); (5) the right to live independently and be included in the community (Article 19 of the CRPD).

In July 2014, Indonesia's House of Representatives (*Dewan Perwakilan Rakyat*) approved a new Mental Health Law following advocacy and lobbying by a psychiatrist Member of Parliament, Dr Nova Riyanti Yusuf. The new law promised better treatment of people with mental ill-health and intellectual disabilities, including outlawing shackling. In line with the principles of freedom and social justice in the 1945 constitution, the new Mental Health Law built upon previous mental health legislations largely in line with the CRPD. This law was approved a year after India's Mental Health Care Bill (2013) and two years after China's National Mental Health Law (2012). By 2014, three of the world's most populous Middle-income Countries have their own mental health legislation. China, however, began its mental health reforms before the law was passed by the National Assembly (Ma, 2012). In contrast, Indonesia remains waiting for a top-down directive on how to implement the law.

Based on the principles of human rights and recovery, and in line with the WHO Mental Health Action Plan, Indonesia's new Mental Health Law is based on the following premises: justice, humanity, beneficial impact, transparency, accountability, comprehensiveness, protection, and nondiscrimination. Its layout reflects a public mental health model, with a specific focus on health promotion, prevention, intervention, and rehabilitation (Figure 4). The four-fold model is built upon the three-fold principles of prevention, intervention, and rehabilitation from the 1966 Mental Health Law, recognising the need for public education on mental health and efforts to reduce stigma.

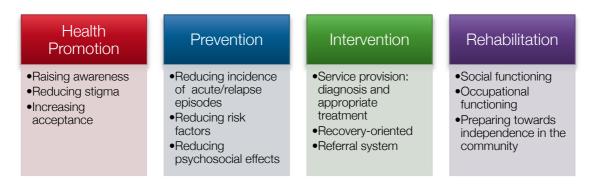


Figure 4. Public Health Model of Mental Health Care Embedded in the 2014 Law

The new law also comes with a set of regulations governing the provision of mental health services, including explicitly banning the practice of *pasung* and stating the requirements for provincial governments to manage and provide primary, secondary, and tertiary care and rehabilitation of people with mental health issues. By 2018, only one province (West Java) had introduced local regulations regarding the provision of mental health services (Arisanti et al., 2018). As it is impossible to meet the required number of qualified mental health professionals within the next few years, provincial governments must consider other solutions to provide mental health care adequately.

In light of the political and structural makeup of Indonesia's current health system, the management of psychiatric disorders seems to require a concerted effort combining deliberate top-down with grassroots initiatives to circumvent the stigma and human rights violations ingrained in traditional beliefs towards mental health disorders. The subsequent process of developing national policies around mental health is an opportunity to bridge cutting-edge research and public policy. Action plans and case studies should accompany the mandate given to provincial governments to finance and provide mental health services. Recognising the general lack of specialist knowledge regarding mental health service frameworks among civil servants in regional government offices, a lag between policy-making and ground-level service provision is expected. This situation presents a golden opportunity for the development of an evidence-base for the clinical and cost-effectiveness of various service frameworks.

1.6 Proposed Solutions

Experts suggested integrating mental health care into primary care, to help bridge this gap (Mendenhall et al., 2014). Recent research established that primary care clinics are the first port-of-call for most people with mental health problems (Kessler and Stafford, 2008). However, diagnosing mental health

problems in primary care is difficult for several reasons. Firstly, most patients present with physical ailments (Allen, 2002, Kessler and Stafford, 2008). Secondly, underlying psychiatric morbidity may not be diagnosed given the time constraint during the consultation (Coyne et al., 2000). Patients may not be familiar with articulating their symptoms, and therefore the onus is on primary care physicians to provide a thorough clinical interview, which may be time-consuming. Thirdly, the majority of primary care physicians report that they could not refer patients on for secondary care (Sorel and Everett, 2011). In addition, when referrals are made, no appointment is ever made for up to 90% of referrals made to offsite practitioners (Callahan et al., 2002, Katon, 1995, Kessler and Stafford, 2008).

These problems are worse in Low and Middle-Income Countries (LMICs) as poverty has been linked to the increased prevalence of mental health problems (Arcury and Quandt, 2007, Rios-Ellis, 2005), and decreased likelihood of access to treatment (Borowsky et al., 2000, Hovey and Seligman, 2006, Miranda and Cooper, 2004, Wang et al., 2005). Despite this, there is good evidence for effective, locally feasible, and affordable treatments for mental health problems in LMICs. Systematic reviews have shown that non-specialist health worker interventions for mental health care in LMICs are clinically effective (Caulfield et al., 2018, van Ginneken et al., 2011). Several studies have shown the provision of mental health services in primary care is both effective and efficient (Bao et al., 2013, Katon et al., 2002, Sorel and Everett, 2011).

In the integration of mental health care into primary care, the multimorbidity of mental and physical illnesses is unavoidable. A cross-sectional study in Scotland found 23.2% point prevalence rate of multimorbidity among primary care patients (Barnett et al., 2012). The same study found that the presence of a mental health disorder increased as the number of physical morbidities increased. The rate of multimorbidity increased along with economic deprivation, and separately, age. This is relevant for *Puskesmas*-attending patients, as the free (or heavily subsidised) medical treatment attract patients from lower socio-economic status. For multimorbidity, the integration of mental health into primary care is a feasible solution to its own problem. A trial conducted in in North West England found good evidence supporting a collaborative care model integrating physical and mental health treatment in primary care for multimorbidity, resulting in mental health symptom reduction and better self-management of chronic diseases (Coventry et al., 2015).

Embedding a screening procedure into primary care could help early identification, intervention, and prevention of common mental disorders, including anxiety and depression (Baksheev et al., 2011). For a screening procedure to be effective, a reliable screening instrument is necessary, and its optimal threshold needs to be determined. Resources for effective intervention must also be in place.

Though many academic articles, white papers, and media attention focus on the human rights violations towards people with mental health issues in Indonesia, only a handful focus on providing potential solutions. Two primary mental health service frameworks currently running in Indonesia should be considered: the task-shifting framework and the specialist framework. Both frameworks have not been evaluated in the Indonesian context, despite their potential to be the framework of choice for other provincial and district governments to adopt.

The task-shifting framework was pioneered in Aceh following the Boxing Day tsunami, and has undergone an evolution since 2004. As there was a lack of qualified mental health professionals who could provide post-disaster psychiatric intervention, cadres of health workers were trained to identify mental health issues, and general practitioners and nurses were trained to provide mental health services. The task of managing psychiatric disorders, traditionally the remit of specialist mental health professionals, is shifted to primary care clinicians, including general practitioners and nurses. The Ministry of Health, under the Directorate of Mental Health, subsequently managed the training of general practitioners and nurses. In 2015, 47% of *Puskesmas* in the country had at least one staff member who have been given additional mental health training: Community Mental Health Nursing (CMHN).

The WHO Mental Health Gap Action Programme (WHO mhGAP) was launched in 2008. The programme aims to support countries in the scaling up of services for mental, neurological, and substance use disorders (MNS). The programme focuses on the delivery of pharmacological and psychosocial interventions in non-specialised healthcare settings. The WHO mhGAP manual contains the following modules: depression, psychoses, epilepsy, child and adolescent mental and behavioural disorders, dementia, disorders due to substance use, self harm/suicide, as well as other significant mental health complaints. Both the Intervention Guide and the Training Manual are freely available on the WHO website.

In 2015, the Ministry of Health revised the curriculum for the training of *Puskesmas* GPs and Nurses to follow the adapted WHO mhGAP Training Manual. Since then, the Directorate of Mental Health has been systematically conducting adapted WHO mhGAP training in various provinces, to pairs of *Puskesmas* GPs and Nurses, with training costs covered by the country's health budget. A sample training schedule is available in Appendix A. There was no study on the effectiveness of the task-shifting programme in Indonesia, prior to the attempt described in this thesis. Additionally, to date there is no attempt to determine adherence to the intervention guide. This reflects the practicality decision-making for public policy: available funds were directed to what policy-makers considered crucial which in this case is training.

While the first WHO mhGAP Intervention Guide (mhGAP-IG) has been used by over 80 countries and translated into more than 20 languages, few research studies had directly addressed the utility of the mhGAP framework in LMICs, highlighting the pressing need for evidence (Dua et al., 2016). Studies on barriers and facilitators to mhGAP-IG use, adherence, and patient outcomes are particularly required, to inform local, regional, national, and global improvements. A recent systematic review of the WHO

mhGAP evidence from LMICs found 33 published literature reporting training courses (15 articles), clinical implementations (9 articles), country contextualisation (3 articles), economic models (3 articles), uses as control interventions (2 articles) and use in developing a rating scale (Keynejad et al., 2018). The same review underlined the pressing need for an understanding of contextual challenges in the field, detailed protocols, qualitative studies, as well as randomised controlled trials – all of which would be attempted by this thesis and other studies conducted alongside, for the Indonesian context.

On the other hand, integrating psychology in primary care is in line with current thinking which conceptualises primary care as a biopsychosocial rather than a biomedical field (Bluestein and Cubic, 2009). The presence of psychologists in primary care setting combines the underlying concepts of the Chronic Illness and Integrated Care models through facilitating shared decision making between primary care providers and behavioural care providers, addressing the realities of primary care (Bluestein and Cubic, 2009). An integrated care model in high income countries has been shown to be cost-effective (Liu et al., 2003), matches patients' preference (especially older patients) (Areán et al., 2002) leading to increased utilisation of mental health care (Hedrick et al., 2003) and results in higher treatment adherence and better clinical outcomes (Katon et al., 2002).

From on an interview with Professor Laksono Trisnantoro, former Dean of Medical School, Universitas Gadjah Mada, In 2004, the Sleman District Health Office (within Yogyakarta province), in collaboration with the Centre for Public Mental Health (Universitas Gadjah Mada), initiated the integration of clinical psychologists within primary care (Retnowati, 2011). The presence of clinical psychologists in Sleman district was for the first five years (2005-2010) fully funded by Professor Trisnantoro's grant from World Vision, and for the next five years (2010-2015), the presence of clinical psychologists in Sleman and Kota districts was 50% funded by the grant, and 50% funded by the district health budget. By 2016, all 43 *Puskesmas* in the Sleman and Kota districts (two out of five districts in the Province Yogyakarta), had employed a Clinical Psychologist to provide basic mental health services at community level. Their salaries are now 100% funded by the district health budget. These psychologists submit two reports annually to the Centre for Public Mental Health, a specialised unit within the Faculty of Psychology at Universitas Gadjah Mada, which also manages their continual professional development. In 2017, this programme was also rolled out to a third district within the province, Bantul district.

While the resources of individual provinces across Indonesia are different, both service provision frameworks above can be adapted to local contexts. Both frameworks increase the accessibility of mental health services by providing it at a non-stigmatised, affordable, and local setting, such as primary care clinics. The task-shifting framework is a top-down initiative, but the specialist framework is an example of a bottom-up initiative. The high rate of service utilisation of *Puskesmas* across the country shows that community health centres are potentially feasible tools in the effort to bridge the Treatment Gap.

1.7 The Case for Screening

While there is momentum to improve the mental health system, including integrating mental health services within primary care, there remains the worldwide problem of timely and accurate identification of psychiatric disorders. Illness has been defined as the subjective experience of symptoms by the patient and their social network, which Arthur Kleinman terms "the innately human experience of symptoms and suffering... how the sick person and the members of the family or wider social network perceive, live with, and respond to symptoms of disability" (Kleinman, 1988). Clinicians bridge the gap between a patient's subjective experience of illness and the biomedical model of diseases – an especially challenging task in mental health.

The process of identifying mental (psychiatric) disorders is complex and is recognised as one of the critical issues for healthcare. Limited understanding of the underlying physiological mechanisms behind mental disorders and the very nature of their definitions mean diagnoses must rely primarily on observations and self-reports. The current (and perhaps enduring) lack of a biomedical model for many of these disorders means that clinicians as a group are still dependent on subjective report for their definition of pathology, which may or may not transcend cultural boundaries. The subjective experience of the patient, the symptoms of the illness, are therefore the signs of the disease.

Under-diagnosis of psychiatric disorders has been partly attributed to the reluctance of clinicians to move away from their conviction that diagnoses should be based on underlying physiological mechanisms, rather than symptoms of illness (Kupfer et al., 1989). Given the lack of studies in Indonesia and other LMICs, available studies from high-income countries are instead presented to illustrate potential mechanisms behind this phenomenon. Several studies report that primary care physicians are especially reluctant to diagnose depression and do not recognise it, resulting in an average delay in diagnosis in high-income countries for major depression of approximately five years (Mitchell et al., 2009, Tyrer, 2009). In a review of 23 studies, Mitchell and colleagues (2009) found that General Practitioners could identify the mild signs of depression in only 1 of 3 cases. Inherent stigma among clinicians based on discomfort regarding the lack of understanding of the biological basis of mental health conditions could inhibit General Practitioners' ability to diagnose (Hyde et al., 2005). In a European qualitative study examining doctors' attitudes towards different illnesses, Haldar and colleagues found that many medical practitioners across disciplines viewed mental disorders as "illegitimate" or less prestigious than physical illnesses (Haldar et al., 2015). Legitimacy here refers to Parson's sick role (1951), which is combined with the idea of stigma (Goffman, 1963) and seriousness as the three elements of a sociological classification of diseases (Freidson, 1970). Borrowing from the labelling theory model, Freidson argues that diseases which come closest to the ideal sick role are serious, often acute, without stigma, and (therefore) highly legitimate.

Though lacking in "legitimacy", psychiatric disorders are estimated to be present in around 20-36% of patients attending primary care settings globally, and when untreated, result in significant suffering and

growing healthcare costs (Schmitz et al., 1999a, Spitzer et al., 1994). Improving ways to identify people at risk of psychiatric disorders is a feasible strategy to help bridge the Treatment Gap and reduce suffering experienced by people with psychiatric disorders (Lund et al., 2012). Screening for symptoms of psychiatric disorders among primary care patients may be a practical approach for General Practitioners as it offers a somewhat objective way of identifying those who might benefit from further assessment.

1.8 Aims and Objectives

This thesis capitalises on recent developments to study two models of basic psychiatric care frameworks co-located in primary care (*Puskesmas*). With the primary aim of evaluating patient outcomes related to the implementation of both frameworks, this thesis adopts a methodical approach which would enable the replication of effective programme in other contexts within Indonesia. This thesis hopes to present an evaluation of the current situation (pragmatic trial) without introducing additional variables such as monitoring and reporting, which might alter clinicians' attitudes towards their patients. As both frameworks co-exist in Yogyakarta, a province within Indonesia, the province was selected to be the trial setting.

In embedding basic psychiatric care into the primary care system, a screening procedure would assist in the identification of primary care patients with potential psychiatric disorders. This thesis begins by testing the utility of the 12-item General Health Questionnaire (GHQ-12) as a screening tool, establishing an appropriate threshold associated with the presence of psychiatric morbidity for the Yogyakarta *Puskesmas* context. A Receiver Operating Curve (ROC) study described in Chapter 2 was undertaken to achieve this.

Alongside the ROC study, a cluster randomised controlled trial evaluated clinical and cost-effectiveness of both the adapted WHO mhGAP and the Specialist Framework in Yogyakarta in terms of patient outcomes. Chapter 3 of this thesis describes the pilot study and the trial protocol. Clinical effectiveness is assessed by looking at patient outcomes at six months after enrolment. Patient outcomes examined include mental and social health symptoms, disability rating, and health-related quality of life. Cost-effectiveness study examines health systems costs associated with patient improvements at six months after enrolment. As a pragmatic trial, clinicians' adherence to the WHO mhGAP Intervention Guide was not enforced, in line with current stance of the Ministry of Health. Chapter 4 presents the trial results.

This thesis concludes with a discussion of findings, strengths, and limitations of study approaches, as well as potential implications. The WHO increasingly acknowledges the impact of 'real world' contextual factors on the implementation of evidence-based health interventions in clinical practice (Peters et al., 2014). Results of the endeavour detailed in this thesis will not only inform the scale-up of

mental health service provisions within Indonesia but also contribute to the limited literature on 'real world' implementation of evidence-based mental health interventions in clinical practice.

2 THE GHQ-12 AS AN EFFECTIVE MENTAL HEALTH SCREENING TOOL FOR THE INDONESIAN PRIMARY CARE POPULATION

This chapter determines the threshold associated with optimum sensitivity and specificity for the utility of the GHQ-12 to establish its potential as a screening tool for psychiatric morbidity among adult primary care patients in Yogyakarta. The threshold determined would be used as a screening criterion for the cluster randomised controlled trial described in Chapters 3 and 4.

The prospective Receiver Operating Characteristic study described in this chapter was conducted with 676 primary care patients. I compared participants' GHQ-12 scores and psychiatric diagnosis based on face-to-face clinical interviews with medical practitioners using the Revised Clinical Interview Schedule (CIS-R). Patients were registered with 28 primary care clinics randomly selected for the study. From all adult patients attending the clinics, 13.7% agreed to participate (676/ 4944 consecutive patients approached), with the median age of 46 years old (range 18 – 82 years), and 67% women. Median GHQ-12 score for our primary care sample was 2, interquartile range 4. Mean score was 2.46 (SD=2.50). The internal consistency of the GHQ-12 was good (Cronbach's α =0.76). Results from the ROC curve indicated that the GHQ-12 is 'fairly accurate' when discriminating primary care patients with indication of mental disorders from those without. The optimal threshold of the GHQ-12 was either 1/2 or 2/3 point depending on the intended utility, with a Positive Predictive Value of 0.68 to 0.73 respectively.

Results of the study detailed in this chapter led to the conclusion that the Indonesian version of the GHQ-12 could be used to screen primary care patients at high risk of mental disorders although with significant false positives if reasonable sensitivity is to be achieved.

2.1 RATIONALE

Experts suggested integrating mental health care into primary care, to help bridge Treatment Gap (Mendenhall et al., 2014). Embedding a screening procedure into primary care could help early identification, intervention, and prevention of common mental disorders, including anxiety and depression (Baksheev et al., 2011). For a screening procedure to be effective, a reliable screening instrument is necessary, and its optimal threshold needs to be determined. Resources for effective intervention must also be in place.

The General Health Questionnaire (GHQ) is a self-administered screening tool designed to detect current state mental disturbances and disorders in the primary care setting (Goldberg and Hillier, 1979). The GHQ has been translated into 38 languages since its development, indicating its face validity across cultures (Jackson, 2007). While the GHQ was originally developed as a 60-item questionnaire, several abridged versions (30-item, 28-item, 20-item, and 12-item) are currently available. The 12-item version was adopted as a screening tool in a multi-country World Health Organization (WHO) study of mental disorders in the primary care setting, as it was considered the best validated among similar inventories (Goldberg et al., 1997, Schmitz et al., 1999b, Üstün and Sartorius, 1995).

The twelve-item General Health Questionnaire (GHQ-12) is intended to screen for general (nonpsychotic) psychological morbidity among primary care patients (Goldberg et al., 1997). Items on the GHQ-12 are rated on a 4-point scale using a time-frame of 'in the last two weeks'. There are two ways of scoring the GHQ-12: the bimodal GHQ scoring method (0-0-1-1) recommended by the test authors for use in clinical settings; and the Likert scoring method (0-1-2-3) which is commonly used in research settings.

A review of international validity studies of GHQ-12 conducted 20 years ago, including in low and middle-income countries, of GHQ-12, reported that the optimal threshold varied from 1/2 to 6/7, with the most common cut-off being 2/3 (Goldberg et al., 1997). Adding a further 17 international studies revealed a variation from 0/1 to 5/6 (Goldberg et al., 1998). In later studies, the distribution ranged from 1/2 to 3/4 (Cano et al., 2001, Caraveo-Anduaga et al., 1998, Schmitz et al., 1999a, Yusoff, 2010). These differences may be the result of varying prevalence rates of mental disorders and comorbidity, as well as the populations in which the scale was administered and cultural influences (Lewis, 1992).

The Indonesian Ministry of Health adopted the GHQ-12 for its 2007 Basic Health Research, a nationwide survey of the socio-cultural determinants of health (Kemenkes, 2008). As such, an Indonesian version has been available for some time. However, its reliability and validity in the primary care setting had not been evaluated, and a validated threshold has not been established. A validated, appropriate country cut-off is needed to identify patients with potential mental disorders effectively. This study aimed to determine appropriate thresholds for optimum sensitivity and specificity of the GHQ-12 in adult Indonesian primary care patients. Threshold determined would be a screening criterion for the cluster randomised controlled trial described in subsequent chapters. A Receiver Operating Characteristic (ROC) study is a valuable method to determine appropriate thresholds. ROC curves have been widely used to describe and compare the performance of diagnostic algorithms (Hanley and McNeil, 1983).

2.2 METHODS

2.2.1 Design

A prospective ROC study was conducted to test the screening accuracy of the GHQ-12 and determine the point at which the balance between sensitivity and specificity is optimised. The curve is created by plotting the true positive rate (sensitivity) against the false positive rate (1-specificity) for each discrimination threshold score. The area under a ROC curve represents the probability that a randomly chosen subject is correctly rated or ranked with greater suspicion than a non-diseased subject (Hanley and McNeil, 1982). The size of the area under the curve is directly proportionate with diagnostic accuracy, with the most appropriate threshold value being the closest to the point of perfect classification which represents 100% sensitivity and 100% specificity. This threshold can then be recommended for screening use in primary care (clinical) settings in Indonesia.

2.2.2 Participants

Participants were recruited over a period of two weeks (December 2016) from 28 *Puskesmas* in Yogyakarta, Indonesia, as part of a cluster randomised controlled trial (NCT02700490, clinicaltrials.gov). 13.7% (676) agreed to take part out of 4944 consecutive primary care adult attendees. Patients self-completed the GHQ-12 before an in-depth psychiatric interview with a General Practitioner.

2.2.3 Measures

General Health Questionnaire (GHQ-12)

The primary measure being assessed for its screening accuracy in Indonesian, as translated by the Indonesian Ministry of Health and used in the nation-wide Basic Health Research (Kemenkes, 2008) was the GHQ-12. As this study took place in a 'real life' clinical setting, the GHQ scoring method (0-0-1-1) was utilised.

As the aim of this study was to examine the adequacy of the GHQ-12 as a diagnostic tool, lifetime diagnoses were not taken into consideration. Instead, current mental health status was evaluated.

Clinical Interview Schedule-Revised (CIS-R)

For the evaluation of psychological morbidity, clinicians used the Clinical Interview Schedule-Revised (CIS-R) (Lewis and Pelosi, 1990) and any further clinical interview questions (as required), following the protocol of similar validity studies in Italy, England, Brazil, and Chile (Goldberg et al., 1998). The CIS-R (Lewis and Pelosi, 1990) is a fully structured diagnostic instrument that was developed from an existing instrument, the Clinical Interview Schedule (CIS), which was designed for the use of clinically experienced interviewers (Blay et al., 1991). The CIS was revised and developed into a fully structured interview to increase standardisation and to make it suitable to be used by trained lay interviewers in assessing minor psychiatric morbidity in the community, general hospital, occupational and primary care research. As the CIS-R specifically diagnoses mood and anxiety disorders, participants with an indication of other disorders (psychosis, sleep disorders, dementia) were asked additional questions which enabled the interviewers to establish an ICD-10 diagnosis. For our sample, the interview was conducted by general practitioners or clinical psychologists employed by each primary care clinic. The psychiatric diagnostic criteria of the ICD-10 are widely used in the Indonesian, public healthcare services as the Indonesian manual for diagnosing psychiatric disorders (Pedoman Panduan Diagnosa Gangguan Jiwa) released in 1993 and used by medical doctors and psychologists, was a translation of the ICD-10 released by the WHO in 1992.

2.2.4 Data Analysis

The required sample size for a prospective ROC study of a single diagnostic test (Obuchowski, 1998) allowing a type I error of 0.05 and a power of 0.80, with the more conservative AUC1 of 0.80, AUC0 of 0.70, and the allocation ratio of 4 (prevalence of common psychiatric disorders is estimated to be 20% in the primary care population, thus the prevalence of non-diseased is estimated at 80%) was 370 subjects (74 clinically confirmed cases and 296 clinically confirmed non-cases). The sample size calculation confirmed that the sample size recruited as part of the cluster randomised controlled trial to evaluate the clinical and cost effectiveness of primary mental health interventions in Yogyakarta is sufficient for this ROC study.

I used SPSS version 24.0 to calculate descriptive statistics and perform a ROC curve analysis on the data, as it is a commonly used method for visualising performance ability and grouping classification (Fawcett, 2006). The ROC analysis plots a test's true positive rate (sensitivity) against its false positive rate (1-specificity) (Obuchowski and McClish, 1997). The area under the curve (AUC) ranges from 0.5 for models with no discrimination ability, to 1 for models with perfect discrimination ability (Miska and Jan, 2005). A ROC curve that is near the point of perfect classification (upper left corner of the ROC space) is considered superior for detection performance (Metz, 1978).

In addition, the positive predictive value (PPV) describes the proportion of all positive results that are correct; while the negative predictive value (NPV) represents the proportion of all negative results that is correct. These predictive values are dependent on the prevalence of mental disorders in the study sample (Zweig and Campbell, 1993).

Total GHQ-12 scores were utilised as the test variable. The bimodal scoring method (0-0-1-1) was used as the study was conducted in a clinical setting. Two-by-two contingency tables were created by cross-tabulating diagnostic outcomes (the presence or absence of any mental disorders according to ICD-10) and the GHQ-12 screening outcomes (positive or negative screening on the GHQ-12). The gold standard against which the GHQ-12 was tested was the presence of diagnosis following an in-depth psychiatric interview using the CIS-R.

2.3 RESULTS

2.3.1 Sample Characteristics

Participants were aged between 18 and 82 years old (median 46). From 4944 primary care patients approached, 676 consented to participate (452 women; 224 men). The mean score for women was 2.60 (SD=2.55) and for men 2.16 (SD 2.38). The median and interquartile range for women were 2 and 4, and for men 2 and 3. The difference in mean scores between women and men was not significant (t=2.174, p=0.30).

The table below presents participants' demographic characteristics (age, marital status, education level), as well as their GHQ-12 scores by gender.

	Wome	en (N=452)	Men (N	=224)	Total (N	J=676)
	N	%	Ν	%	N	%
Age (11 missing)						
18-29	117	26.2	47	21.5	164	24.7
30-39	62	13.9	24	11.0	86	12.9
40-49	118	26.5	28	12.8	146	22.0
50-64	119	26.7	81	37.0	200	30.1
65+	30	6.7	39	17.8	69	10.4
Marital Status (2 missing)						
Unmarried	77	17.1	54	24.1	131	19.4
Married	319	71.1	163	72.8	482	71.7
Separated/Divorced/Widowed	53	11.8	7	3.1	60	8.9
Education (6 missing)						
Elementary	94	21.0	33	14.9	127	19.0
Middle School	104	23.2	43	19.4	147	21.9
High School	157	35.0	97	43.7	254	37.9
Diploma	20	4.5	16	7.2	36	5.4
University	48	10.7	27	12.2	75	11.2
Others	25	5.6	6	2.7	31	4.6
GHQ-12 Score						
Mean (SD)	2.60 (2	2.55)	2.16 (2.	38)	2.46 (2.	50)
Median (IQR)	2.00 (4	4.00)	2.00 (3.	00)	2.00 (4.	00)

Table 2. Total and by gender socio-demographic characteristics and GHQ-12 scores (0-0-1-1 scoring)

Almost one in five (19%) had only completed elementary-level education. A further 21% completed Junior High School, and 37.9% completed High School. The rest (22.1%) completed undergraduate or postgraduate degrees. There is no statistically significant difference in mean and median scores between those who received education beyond the High School level, and the rest of the population (t=2.72, p=0.07). Fewer than 5% received less than six years of formal education.

Thirty-two participants (4.7%) were born outside Java and did not belong to the Javanese ethnicity. They represented other remote parts of Indonesia including Aceh (Western-most province) and Papua (Eastern-most province). In Indonesia, 42% of the population identify as ethnic Javanese.

2.3.2 Reliability

The internal consistency coefficients (Cronbach's alpha) of the GHQ-12 for bimodal scoring (0-0-1-1) was 0.76, indicating satisfactory internal consistency.

2.3.3 Validity coefficients and area under the ROC curve

Table 3 shows the prevalence of ICD-10 psychiatric diagnoses and GHQ-12 mean scores for adult Indonesian primary care patients.

For those with a severe depressive episode, the GHQ-12 mean score was 8.40 (SD=3.78), median of 10 and interquartile range of 7. For those with Comorbid Anxiety and Depression, the GHQ-12 mean score was 3.95 (SD=2.46), the median of 3 and Interquartile Range of 3. For those with the general anxiety disorder, the GHQ-12 mean score was 4.56 (SD=3.07), the median of 6 and interquartile range of 9.

Table 3. Total and by gender prevalence of psychiatric diagnoses and mean GHQ-12 scores
(bimodal scoring) of respondents interviewed with CIS-R and further clinical interviews

	Women	Men	Total	GHQ-12	GHQ-12
ICD-10 diagnoses	N (%)	N (%)	N (%)	M±SD	Median (IQR)
Mild depressive episode	7 (1.0)	29 (4.3)	36 (5.3)	3.42±2.60	2 (3)
Moderate depressive episode	1 (0.1)	11 (1.6)	12 (1.8)	5.42±2.91	7 (4)
Severe depressive episode	1 (0.1)	4 (0.6)	5 (0.7)	8.40±3.78	10 (7)
Mixed anxiety and depression	31 (4.6)	71 (10.5)	102 (15.1)	3.95±2.46	3 (3)
General anxiety disorder	7 (1.0)	18 (2.7)	25 (3.7)	4.56±3.07	6 (2)
Panic disorder	5 (0.7)	15 (2.2)	20 (3.0)	3.55±3.27	5 (6)
Social phobia	7 (1.0)	13 (1.0)	20 (3.0)	2.50±1.61	2 (1)
Agoraphobia	1 (0.1)	0 (0.0)	1 (0.1)	$2.00{\pm}0.00$	2 (0)
Specific isolated phobia	2 (0.3)	6 (0.9)	8 (1.2)	3.25±0.89	3.5 (2)
Obsessive compulsive disorder	0 (0.0)	3 (0.4)	3 (0.4)	5.67±1.16	5 (0)
Diagnosis of other disorders	15 (2.2)	54 (8.0)	69 (10.2)	3.00±2.58	2 (3)

Mean and median scores for those with a diagnosis (cases) compared to those who do not meet the ICD-10 diagnostic criteria (non-cases) are shown in Table 4.

	Women		Men		All		
		Ν		Ν		Ν	
Mean (SD)							
Cases	3.70 (2.66)	235	3.61 (2.64)	89	3.68 (2.65)	324	
Non-cases	1.40 (1.79)	216	1.21 (1.58)	135	1.33 (1.71)	351	
Median (IQR)							
Cases	3 (3)	235	3 (3)	89	3 (3)	324	
Non-cases	1 (2)	216	1 (2)	135	1 (2)	351	

Table 4. GHQ-12 mean and median scores for non-cases vs cases meeting any ICD-10 diagnostic criteria during the sampling period, Bimodal scoring (0-0-1-1)

The GHQ-12 mean for cases (48%) was 3.68 (SD=2.65), and the mean for non-cases (52%) was 1.33 (SD=1.71). The group meeting diagnostic criteria had significantly higher mean scores than those without a diagnosis (t=-13.773, df=673, p<0.001).

The GHQ-12 median for cases (48%) was 3, Interquartile Range of 3, and the median for non-cases was 1, Interquartile Range of 2. The group meeting diagnostic criteria had significantly higher median scores than those without a diagnosis (Mood's Median Test χ^2 =111.07, df=1, p<0.001).

The threshold values, sensitivity, specificity, PPV, NPV, and AUC of the GHQ-12 based on diagnostic groups (at two-week prevalence) are summarised in Table 5.

ICD-10 Diagnoses	Threshold	SE	SP	PPV	NPV	AUC
Mood Disorders	1/2	0.774	0.433	0.104	0.957	0.702
	2/3	0.717	0.634	0.143	0.963	
Mixed Anxiety and Depression	1/2	0.902	0.474	0.234	0.965	0.725
	2/3	0.686	0.659	0.263	0.922	
Anxiety Disorders	1/2	0.805	0.446	0.157	0.947	0.661
	2/3	0.597	0.624	0.172	0.924	
Any diagnosis	1/2	0.824	0.641	0.679	0.789	0.787
	2/3	0.599	0.798	0.732	0.683	

Table 5. Performance and ROC area of the GHQ-12 (bimodal scoring)

The ROC analysis indicated that the optimal cut-off point for the identification of any diagnosis was 1/2. Sensitivity was 82% while specificity was 64%. The AUC of 0.79 indicates that GHQ-12 is 'fairly accurate'. The traditional established point system for the AUC specifies that AUC of at least 0.70 is required to ensure fair accuracy (Zweig and Campbell, 1993). The ROC curve for any ICD-10 diagnosis is presented in Figure 5.

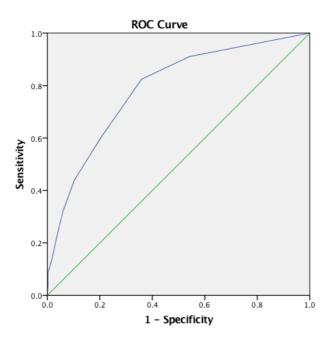


Figure 5. ROC curve of GHQ-12 for ICD-10 psychiatric diagnoses. Bimodal scoring 0-0-1-1.

2.4 DISCUSSION

The GHQ-12 was found to have good reliability (inter-item consistency) within the Yogyakarta primary care setting. It is also a 'fairly accurate' screening tool with predictive power for ICD-10 psychiatric diagnosis of nearly 0.8 (AUC=0.78). The recommended optimal threshold differs depending on the objectives for using the GHQ-12. For use in *Puskesmas*, the goal can be to comprehensively screen for any ICD-10 psychiatric diagnosis even at the risk of a high false positive rate. As such, the optimal threshold for the bimodal scoring is 1/2 points. If the goal is for better discrimination of mood disorders and anxiety disorders (Goldberg et al., 1998) it may be more appropriate to adopt the more stringent threshold of 2/3 points.

While for practicality, a more conservative cut-off score will reduce the absolute number of psychiatric interviews to be conducted, one must critically form a decision with the awareness that there are people who would otherwise be diagnosed, who did not meet the screening criteria (False Negatives). Using a cut-off score of 2, the False Negative Rate is 20%, while with a more conservative cut-off score of 3, the False Negative Rate is 31%. If the goal of screening for psychiatric disorders in primary care is to help bridge Treatment Gap, the recommended threshold is 1/2 points, where a score of 2 or above is 'positive' for at risk of psychiatric disorders.

The analysis confirms that the Indonesian version of the GHQ-12 can be useful in screening for psychiatric morbidity among primary care patients. For clinical services, an optimal threshold score for any tool used in screening for mental disorders is necessary to best distinguish at-risk individuals from the remaining population (Mann et al., 2005). A screening tool such as the GHQ-12 may have considerable utility within primary care in Indonesia, particularly as it may have the potential to increase

efficiency within an overburdened healthcare system. It could only be introduced, however, if the adequate services to support those screened are in place (Wilson and Jungner, 1968).

The medians of participants with a psychiatric diagnosis (3) and those without (1), shows that while the difference of one or two scores may seem trivial, it was sufficient to highlight potential 'cases' from other primary care patients. The use of a 'fairly accurate' screening tool within a clinical setting would facilitate the swift identification of primary care patients at risk of psychiatric morbidity, bolstering the confidence of primary care doctors to conduct an in-depth psychiatric interview without fear of making a mistake or offending their patients. Those who screened positive should be provided additional information regarding common psychiatric disorders (Kelly et al., 2007). Screening, coupled with increased mental health literacy could facilitate the early identification and intervention of psychiatric disorders, which would help bridge Indonesia's enormous Treatment Gap.

While this study's strength lies in its validation of the utility of the GHQ-12 in Indonesia's primary care setting, this study is not without its limitations. The length of waiting time means more patients who agreed to take part in the study left before completing the standardised psychiatric interviews, due to other commitments such as work. Women in caregiving roles typically brought their dependent children along to the *Puskesmas*. The manifestations of gender role are reflected in the smaller number of men participating in the study (n=224) compared to women (n=452). Women have been shown to be more willing to access mental health services than men (Gove, 1984, Mackenzie et al., 2006).

As this study took place in real life settings, I observed that medical consultations including the standardised psychiatric interview took between 20 to 60 minutes longer, depending on the complexity and severity of symptoms to be addressed. At some clinics, patients meeting the screening criteria were asked to wait for all other patients to have their consultations, drawing sharp criticisms from patients who had to wait hours for their consultations. In other clinics, one GP on duty was assigned to handle all patients requiring a psychiatric interview, while all other patients had consultations with other GPs – a seemingly more realistic pathway.

While this study confirms the efficacy of the Indonesian version of the GHQ-12 for the Indonesian primary care population, it is not necessarily generalisable for whole populations for general screening, as opposed to primary care attendees. Further research into the utility of the GHQ-12 to accurately screen for mental disorders among the non-primary care population should be attempted. It should be noted that although the GHQ-12 identifies at-risk individuals, to establish an ICD-10 diagnosis requires a full psychiatric interview with qualified clinicians.

Introduction of screening for mental disorders could have major implications for services, both in primary care, ancillary services to provide effective interventions such as CBT, and secondary care psychiatric services. Indonesia's current mental health system would need to be reviewed to assess in what ways it could be strengthened to provide optimal services, given the ongoing systematic roll-out

of the adapted WHO mhGAP framework to provide mental health management services in primary care clinics across the country. If screening were to be implemented across primary care clinics in Indonesia, it is possible its impact would be viewed with concern. Understandably, in clinics with significantly fewer resources, the health workforce is limited. Increased consultation time, increased waiting time, and possibly increased working hours for clinicians are but some of the issues anticipated, which might lead to rejection of the development.

The benefits of screening for mental disorders in primary care must be weighed against other practical considerations. Nonetheless, in Indonesia, where the Treatment Gap for mental disorders is above 95% (Kemenkes, 2012), the benefits could potentially outweigh the disruption of implications for service.

3 TRIAL PROTOCOL

3.1 Study Design

This study ("the trial") set out to compare patient outcomes following usual care either by primary care doctors additionally trained in the Indonesian-adapted WHO mhGAP framework or clinical psychologists in the Specialist Co-location framework through a **pragmatic**, two-arm **cluster randomised controlled non-inferiority trial**. This study design enabled an examination of patients derived from whole populations in a 'real world' setting.

A standard randomised controlled trial (RCT) would require both frameworks of services to be provided within each site, i.e. the *Puskesmas* unit. Within the context of this trial, participants randomised to another treatment group would be asked to travel to another location if the current *Puskesmas* does not provide the framework. Having both treatment frameworks within a *Puskesmas* unit was not desirable due to potential contamination between intervention and control participants. Contamination of control participants would have two effects: reducing the point estimate of an intervention's effectiveness and, as a result, a higher likelihood of type II error. Considering potential contamination, a pragmatic CRCT design was chosen, despite requiring a bigger sample size for the same statistical power and the possibility of increased recruitment bias.

A non-inferiority trial was chosen to test whether either framework is better than the other, for all outcomes. This type of trial is frequently used where the use of a superiority trial against a placebo control (e.g. no treatment) is considered unethical.

The primary outcome was the health and social functioning of participants as measured by the Health of the Nation Outcome Scale (HoNOS) (Wing et al., 1996) and secondary outcomes were disability as measured by WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) (Sousa et al., 2010), quality of life as measured by European Quality of Life Scale (EQ-5D-3L) (Oppe et al., 2007), and cost of intervention evaluated from a health services perspective, which aimed to determine the clinical effectiveness and cost-effectiveness of the adapted WHO mhGAP framework of primary mental health care versus a Specialist framework of care at 6-month follow-up. Both are currently operational frameworks of primary mental health service provision in several *Puskesmas* within one province (Yogyakarta) in Indonesia. The selection of outcome measures was advised by Dr S. Idaiani from the Indonesian Ministry of Health.

The trial protocol was assessed during a University of Cambridge internal examination on 19th November 2015, by Dr Stephen Gillam and Professor Martin Roland.

The trial involved two phases: a pilot study in June 2016 with the objectives to refine data collection procedures and to serve as a practice run for clinicians involved in the trial (Appendix B); as well as a substantive trial beginning in December 2016. This chapter describes the methods and outcomes of the

pilot study, with a focus on the impact on the recruitment strategies used for the substantive trial. Subsequently, this chapter described the methods used for the substantive trial.

3.2 Pilot Study (June 2016)

A pilot study is defined by the UK's National Institute for Health Research (NIHR) as:

"... a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, retention, randomization, treatment, and follow-up assessments all run smoothly."

The pilot study, therefore, resembled the substantive study in most respects, except for follow-up assessments, given the time limitation of the doctoral degree. The recruitment period for the pilot was one week, and was designed to assess three questions:

- 1. Is it feasible to recruit the number of participants required to meet the planned sample size?
- 2. Is the screening and recruitment procedure feasible?
- 3. Do clinicians find it difficult to perform the in-depth psychiatric interview required to formalise a diagnosis, under time pressure?

3.2.1 Results of the Pilot Study

Concerning question 1, the internal pilot proved that recruitment was feasible if conducted over a more extended period and that the planned sample size could be achieved in principle. The pilot recruitment graph is presented in *Appendix C*.

The pilot study was conducted over a period of one week in June 2016. Trained and vetted research assistants checked in for duty every morning at 7 am and were asked to take a self-portrait with a specific object within the *Puskesmas* of their duty. Information on the object, e.g. queue number collection counter, was provided every morning to ensure compliance. A tally of the number of screenings completed was checked against *Puskesmas* attendance at the end of every day, which enabled the calculation of the percentage of adult primary care attendees screened. Research assistants checked out from duty by sending a picture of the empty *Puskesmas* to the PhD Researcher coordinating the study on site. All research assistants were given the same base salary (Rp 100,000 ~ £6, per day), but those on duty at a *Puskesmas* more than three hours' drive from the centre of Yogyakarta were given additional transport allowance of a day's salary. Given the lack of an incentive structure, I observed a steady decrease in the percentage of adult attendees screened daily in some *Puskesmas*, indicating a decline in commitment which prompted me to consider an incentive structure for the substantive study. Nonetheless, 5341 patients were screened within the recruitment week.

The evaluation of question 2 indicated that the provision of one research assistant per clinic to manage the screening of all adult primary care attendees raised minor challenges. As the research assistant had to conduct recruitment by explaining the trial objectives to those meeting the screening criteria, several adult primary care attendees were left unscreened every day. To further complicate matters, older patients required help with reading the screening questionnaire which rendered other patients neglected. It was also tricky for research assistants to manage four separate documents for each patient: screening questionnaire, information sheet, informed consent sheet, and the questionnaire booklet. All this need to be compiled with clinician's assessment following the psychiatric interview. I noticed the potential for the mismanagement of paperwork by research assistants. Despite the challenges, the proposed procedure proved to be feasible. A focus group with five research assistants and local adviser, Dr Bambang Hastha Yoga, discussed potential mitigating strategies for the substantive trial, including having a pair of research assistants per *Puskesmas*, which were eventually implemented in the substantive trial.

The evaluation of question 3 indicated an inconsistency of confidence among clinicians to conduct indepth psychiatric interviews during busy clinic hours. The pilot study highlighted that with limited time, such as during general practitioner's consultation, it was difficult for clinicians to ask questions relating to symptoms of psychiatric morbidity. Given the interest in also conducting a Receiver Operating Curve study on the GHQ-12 (Chapter 2), a gold standard against which the threshold scores could be compared to was required. Given the precedent set by similar studies conducted in sub-Saharan Africa, under the advice of Professor Martin Prince of King's College London, I incorporated the Revised Clinical Interview Schedule (CIS-R) which is a structured interview guide to assess the symptoms of psychiatric disorders efficiently.

Subtle changes to the substantive study were made, including assigning two research assistants per clinic and converting the information sheets, informed consent sheets, questionnaire batteries, and structured psychiatric interview guide into booklet form. In addition, I extended the recruitment period of the substantive study to two weeks. Doubling the number of research assistants and the length of the recruitment period raised logistical and resource challenges, as additional recruitment and training were required in addition to extra research expenses.

3.3 Main Trial Methods

3.3.1 Ethics and governance

Ethics approval for the study was granted by the University of Cambridge Psychology Research Ethics Committee (reference number PRE.2015.108; Appendix D) and Universitas Gadjah Mada (reference number 1237/SD/PL.03.07/IV/2016; Appendix E). Trial insurance further covers investigators and research participants (University of Cambridge Trial Insurance reference number 609/M/C/1510; Appendix F). Ethics approval from all the clusters was not required as each cluster (*Puskesmas*) is a

state-owned clinic funded and managed by district governments. Permission to conduct research at the Province of Yogyakarta including its all five districts was obtained from the Provincial Government Office (reference number 070/REG/V/625/5/2016; Appendix G). This trial is registered with clinicaltrials.gov on 25 February 2016, NCT02700490.

3.3.2 Interventions

3.3.2.1 Experimental Group: Indonesian-adapted WHO mhGAP

The concept of "Treatment Gap" (TG -- % of those unidentified and untreated who might benefit from known treatments) has been identified as a critical issue within global mental health, leading to the WHO response that is the Mental Health Gap Action Programme (WHO mhGAP). The training manual online is available for free download in various languages, at http://www.who.int/mental health/mhgap/training manuals/en/. Since 2008, the WHO mhGAP programme aims to scale up services for mental, neurological, and substance use disorders especially among low and middle-income countries, by providing add-on clinical mental health training to a nonspecialist audience. The intervention guide, first released in 2010, presents integrated management of priority conditions including depression, psychosis, bipolar disorder, epilepsy, developmental and behavioural disorders in children and adolescents, dementia, disorders due to substance abuse, selfharm/suicide and other significant emotional or medically unexplained complaints.

Proposed management of disorders includes psychoeducation, basic and advanced psychosocial interventions, and pharmacological therapy. Advanced psychosocial interventions outlined in the WHO mhGAP WHO Intervention Guide 1.0 listed in the website are (https://www.paho.org/mhgap/en/int management.html - accessed on 26 October 2018) and include: Behavioural Activation, Cognitive Behavioural Therapy, Contingency Management Therapy, Family Counselling or Therapy, Interpersonal Psychotherapy, Problem-solving Therapy, Relaxation Training, and Social Skills Therapy (Figure 6).

The WHO mhGAP framework has been translated to *Bahasa Indonesia* by the Indonesian Ministry of Health in 2015, adapted to the country's context, and systematically introduced throughout the network of 10,000 *Puskesmas* across the country. The implementation of the adapted WHO mhGAP framework aims to reduce Treatment Gap through facilitating early identification and providing basic or initial intervention in primary care. Since its adaptation and adoption in late 2015, Indonesia's Directorate of Mental Health trained between 10 to 20 pairs of *Puskesmas* doctors (general practitioners) and *Puskesmas* nurses from each province every month, alternating between 34 provinces. These *Puskesmas* were chosen at random from all available *Puskesmas*, with the intention of scaling up to all 10,000 *Puskesmas* across the country. The training schedule for this trial, detailing the modules taught, is in Appendix A.

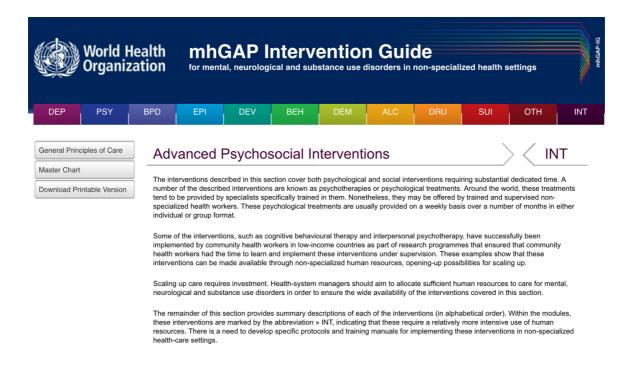


Figure 6. Advanced Psychosocial Interventions recommended in the WHO mhGAP framework (source: WHO)

The Ministry of Health designated the adapted WHO mhGAP framework as a scale-up training for registered medical practitioners and nurses who already had to complete a set of competencies for a comprehensive list of psychiatric conditions prior to gaining a license to practice. The adapted WHO mhGAP modules are therefore, in the Indonesian context, akin to the addition of new tools to an already comprehensive toolbox of a medical doctor. It should be noted that the set of competencies and psychiatric conditions agreed the Indonesian Medical Council and listed in the Indonesian Medical Practitioners Competency Standards specific Indonesian are to the context, (http://fk.ub.ac.id/profesi/wp-content/uploads/2013/10/Standar-Kompetensi-Dokter-Indonesia SKDI-2012-1.pdf) in light of the limited provision of specialist medical care in rural Indonesia, and may not be transferable to other countries. WHO mhGAP practitioners typically employ a combination of basic psychosocial intervention and pharmacological therapy to manage disorders.

For the list of Medical Doctor Basic Licensing core competencies in Table 6, there are four levels of competency determined:

- 1. Level 1: theoretical understanding including biomedical and psychosocial aspects, as well as the ability to explain to patients and family members, colleagues, and other professions including regarding the principles, indications, and complications which may arise.
- 2. Level 2: theoretical and practical understanding, including biomedical and psychosocial aspects, with emphases on clinical reasoning and problem solving, including direct observation experience of patients.

- 3. Level 3: theoretical and practical understanding, including biomedical and psychosocial aspects, with direct practical experience on standardised patients (e.g. through Objective Structured Clinical Examinations (OSCE)).
- 4. Level 4: independent practice, following thorough theoretical and practical understanding and experience, practice under direct supervision, for example through work-based assessments (e.g. through mini-CEX).
 - 1. 4A: core competencies derived upon completing general medical education.
 - 2. 4B: proficiencies derived after internship.

Table 6.	Medical	Doctor	Basic	Licensing	Core	Competencies	for	Psychiatry,	Medical
Practition	ers Comp	etency St	tandard	ls (source: I	ndones	sian Medical Co	uncil)	

Number	Competency	Level of Competence
	ANAMNESIS	
1.	Autoanamnesis with patient	4A
2.	Alloanamnesis with other family members or significant others	4A
3.	Information on primary presenting problem	4A
4.	History of the progress of condition	4A
5.	Gaining meaningful information regarding early childhood development, education, employment, relationship, family life	4A
	PSYCHIATRIC ASSESSMENT	
6.	Assessment of mental state	4A
7.	Assessment of consciousness	4A
8.	Clinical assessment of perception, orientation, and intelligence	4A
9.	Assessment of orientation	4A
10.	Clinical assessment of intelligence	4A
11.	Assessment of form and content of thought	4A
12.	Assessment of mood and affect	4A
13.	Assessment of motor function	4A
14.	Assessment of impulse control	4A
15.	Assessment of judgment ability	4A
16.	Assessment of insight	4A
17.	Assessment of general functioning	4A
18.	Personality assessment (projective, inventory, etc.)	2
	DIAGNOSIS AND IDENTIFICATION	
19.	Establishing a diagnosis based on multiaxial diagnostic criteria	4A
20.	Differential diagnosis	4A
21.	Identifying psychiatric emergency	4A
22.	Identifying physical, psychological, and social problems	4A
23.	Considering prognosis	4A
24.	Determining reason for referral	4A
	ADDITIONAL ASSESSMENT	
25.	Mini Mental State Examination	4A
26.	Home visit, if required	4A
27.	Consultative cooperation in a multidisciplinary team	4A
	THERAPY	
28.	Psychopharmacology therapy (antipsychotic, antidepressant, anticholinergic, sedative, etc.)	3

29.	Electroconvulsive therapy (ECT)	2
30.	Supportive psychotherapy (counselling)	3
31.	Behaviour modification therapy	2
32.	Cognitive Behaviour Therapy (CBT)	2
33.	Psychoanalytic psychotherapy	1
34.	Hypnotherapy and Relaxation therapy	2
35.	Group Therapy	1
36.	Family Therapy	2

For the list of psychiatric conditions which are covered in the Medical Practitioners Competency Standard (Table 7), there are also four levels of competencies expected:

- 1. Level 1: understanding and explaining the clinical presentation of the condition and able to utilise the most suitable method to gain further information on the condition, afterwards determining the appropriate referral pathway for the patient. Graduates of medical school are also able to manage the condition following return from referral.
- 2. Level 2: able to form a clinical diagnosis of the condition, and determining the appropriate referral pathway for follow-up intervention. Graduates of medical school are also able to manage the condition following return from referral.
- 3. Level 3: diagnosing, providing initial intervention, and referring.
 - 3. Level 3A: in non-emergency situations, graduates of medical school are able to form a clinical diagnosis and provide initial intervention. Medical school graduates are then able to determine the appropriate referral pathway for follow-up intervention. Graduates of medical school are also able to manage the condition following return from referral.
 - 4. Level 3B: in emergency situations, graduates of medical school are able to form a clinical diagnosis and provide initial intervention to save patient's life or prevent further harm on the patient. Medical school graduates are then able to determine the appropriate referral pathway for follow-up intervention. Graduates of medical school are also able to manage the condition following return from referral.
- 4. Level 4: diagnosing, managing condition independently, and discharging.
 - 5. Level 4A: core competencies derived upon graduation from medical school.
 - 6. Level 4B: proficiencies derived after internship.

Table 7. ICD-10 Psychiatric Conditions which are part of Medical Doctors' Basic Licensing Core
Competencies (source: Indonesian Medical Council)

umber	Conditions	Level of Competence
	ORGANIC MENTAL DISORDER	
1.	Delirium not induced by alcohol or other psychoactive substances	3A
	MENTAL AND BEHAVIOURAL DISORDERS FROM SUBSTANC	E USE
2.	Acute intoxication of psychoactive substance	3B
3.	Addiction/substance dependency	3A
4.	Delirium induced by alcohol or other psychoactive substances	3A
	PSYCHOSIS	
5.	Schizophrenia	3A
6.	Delusion	3A
7.	Psychotic disorder	3A
8.	Schizoaffective disorder	3A
9.	Bipolar disorder, manic episode	3A
10.	Bipolar disorder, depressive episode	3A
	NEUROTIC DISORDERS, STRESS, AND SOMATOFORM DISOF	RDERS
11.	Cyclothymic disorder	2
12.	Endogenic depression (single episode or recurrent)	2
13.	Dysthymic disorder (neurosis depression)	2
14.	Depressive episode (unclassified)	2
15.	Baby blues (post-natal depression)	2
	ANXIETY AND PHOBIA	
16.	Agoraphobia with or without panic	2
17.	Social phobia	2
18.	Specific phobia	2
	OTHER ANXIETY DISORDERS	
19.	Panic disorder	3A
20.	General anxiety disorder	3A
21.	Mixed anxiety and depression	3A
22.	Obsessive-compulsive disorder	2
23.	Reaction towards stress and adjustment disorder	2
24.	Post-traumatic stress disorder	3A
25.	Dissociative disorder (conversion)	2
26.	Somatoform disorder	4A
27.	Trichotillomania	3A

28.	Personality disorder	2
29.	Gender identity disorder	2
30.	Sexual preference disorder	2
	EMOTIONAL AND BEHAVIOURAL DISORDERS, CHILDHOOD ONSE	ET
31.	Pervasive developmental disorder	2
32.	Mental retardation	3A
33.	Attention deficit disorder, hyperactive disorder (including autism)	2
34.	Conduct disorder	2
	EATING DISORDERS	
35.	Anorexia nervosa	2
36.	Bulimia	2
37.	Pica	2
	TICS	
38.	Tourette's syndrome	2
39.	Chronic motor or vocal tics disorder	2
40.	Transient tics disorder	3A
	EXCRETORY DISORDERS	
41.	Functional encoperasis	2
42.	Functional enuresis	2
	SPEECH DISORDER	
43.	Uncoordinated speech	2
	SEXUAL DYSFUNCTION DISORDER	
44.	Paraphilia	2
45.	Sexual desire or arousal disorder	3A
46.	Female orgasmic disorder or premature ejaculation	3A
47.	Sexual pain disorder (including vaginismus, dyspareunia)	3A
	SLEEP DISORDERS	
48.	Insomnia	4A
49.	Hypersomnia	3A
50.	Sleep-wake cycle disturbance	2
51.	Nightmares	2
52.	Sleep walking	2

In the adapted WHO mhGAP Arm, *Puskesmas* doctors provided pharmacological therapy and/or psychosocial intervention, and/or referred participants to specialist care, as they saw fit. As the trial was designed to reflect real-life practice, *Puskesmas* doctors' choice of intervention was not recorded, nor their utility of the adapted WHO mhGAP modules enforced.

3.3.2.2 Experimental Group: Specialist Co-location

The Specialist framework is the integration of clinical psychologists into the primary care system. It is considered an important step towards scaling up mental health services (Hass et al., 2004). There is good evidence for the effectiveness of psychotherapy delivered in primary care (Hass et al., 2004) and that psychotherapy is as effective as antidepressant medication (Haas, 2004). The co-location of clinical psychologists in primary care improves collaboration and potentially reduce the stigma of mental illness and barriers to care (Derksen, 2009, Elder and Silvers, 2009, Setiyawati et al., 2014).

In 2004, the Sleman District Health Office (within Yogyakarta province), in collaboration with the Centre for Public Mental Health (Universitas Gadjah Mada), initiated the integration of clinical psychologists within primary care (Retnowati, 2011). Following a Bachelor's Degree in Psychology and a Master's Degree in Clinical Psychology, one is required to obtain professional registration as a Clinical Psychologist before seeking employment at a *Puskesmas*. In 2016, psychologists were employed in 43 of 121 *Puskesmas* in Yogyakarta province, specifically in all *Puskesmas* within the districts of Sleman and Kota. In the Specialist framework, clinical psychologists typically use a combination of basic and advanced psychosocial intervention to manage disorders. As the trial was designed to reflect real-life practice, *Puskesmas* psychologists' choice of intervention for research participants was not recorded.

3.3.3 Clinician training

Indonesia's Directorate of Mental Health provided health care providers training in the Indonesianadapted WHO mhGAP framework. In April 2016 (Appendix A), the week-long training of *Puskesmas* General Practitioners took place in Yogyakarta, the province where the trial took place. A psychiatrist from Indonesia's Directorate of Mental Health who had gone through a WHO mhGAP train-the-trainer course conducted the general practitioners' training. The week-long training covered all WHO mhGAP modules, and further incorporated a day of role-playing plus clinical observations in 'real life' setting.

In the Specialist framework, Clinical Psychologists received their mental health assessment and therapy training during their two-year Master's Degree in Clinical Psychology. All psychologists involved in the trial had professional registration as a psychologist in Indonesia. *Puskesmas* psychologists attend regular continuing professional development (CPD) training organised by the Centre for Public Mental Health, a collaborator of this trial.

Before the commencement of the Pilot Study, all clinicians involved in the trial attended a one-day training session on the questionnaires used and on in-depth psychiatric interviews in non-specialised health settings. I conducted the training on the use of questionnaires (WHODAS 2.0, EQ-5D), while a renowned local psychiatrist conducted the training on psychiatric interviewing to complete the primary outcome measure, HoNOS. The training focused on the standardisation of scoring on primary and secondary outcome measures.

Before the commencement of the Substantive Study, all clinicians involved in the trial attended a oneday training session on structured psychiatric interviews in non-specialised health settings (CIS-R). As a psychologist trained in Australia and the UK, with several years of clinical experience, I conducted the training on the administration of the questions and classification of responses, going through each item and facilitating role-play in pairs. Clinicians were also introduced to the research assistants who would be based at their clinics. Clinicians were not trained to score or interpret the result of the CIS-R, as the utility of the CIS-R in the trial was limited to the standardised way of asking clinical questions, analysis of the GHQ-12 as an effective screening tool (Chapter 2), and post-hoc comparisons at the end of the trial period. Clinicians did not use the CIS-R score to establish a diagnosis.

3.3.4 Adherence and fidelity

As this is a pragmatic trial conducted in 'real-life' setting, clinicians were informed that only adherence to the interview protocol (baseline and a follow-up at 6-months) would be enforced, while the onus was on them to ensure service users' treatment adherence, as per usual practice. To facilitate buy-in and avoid the Hawthorne Effect, the trial did not capture any record of clinicians' choice of intervention. The trial did not evaluate the accuracy of diagnosis, nor the appropriateness of the chosen intervention for the diagnosis given. As such, clinicians had the freedom to choose from among their repertoire of interventions, which they developed either through their adapted WHO mhGAP training, clinical psychology training, or any prior training and development activities, without feeling monitored.

Fidelity to chosen treatment procedures was not enforced as this study hoped to reflect actual practices on the ground, which may be adjusted by clinicians based on service users' responsiveness to treatment. As such, the intention-to-treat (ITT) approach is applied to the design, conduct, and statistical analysis of the trial. The ITT approach avoids overoptimistic estimates of the efficacy and feasibility of an intervention resulting from the removal of non-compliers from trials or data analysis (Gupta, 2011).

3.3.5 Setting

Yogyakarta is a province in Java, the only place in Indonesia where the specialist co-location framework is operational at the start of the trial. It is crucial for any 'real life' evaluation to take place in the original setting and for any comparison framework to be introduced to a context as similar as possible to the original (Hohmann and Shear, 2002). There are five districts in Yogyakarta Province: Kota, Sleman, Bantul, Kulon Progo, Gunungkidul, and among them 121 *Puskesmas*. Sleman district in Yogyakarta province also pioneered the specialist primary mental health service model in 2004. Before the start of the trial, the Specialist framework was present in only 43 *Puskesmas* in Kota and Sleman districts.

The adapted WHO mhGAP has been systematically introduced to *Puskesmas* within Indonesia since 2015 but was not yet operational in most *Puskesmas*. The adapted WHO mhGAP framework was introduced to *Puskesmas* in Yogyakarta in an experimental manner (randomised), enabling a pragmatic cluster randomised trial to take place.

The trial took place in primary care clinics (*Puskesmas*) in Yogyakarta province. Stratified random sampling was considered the optimum allocation for the estimation of population means when considering a multivariate problem. The *Puskesmas* were assigned to each treatment arm in a 1:1 ratio. The number of *Puskesmas* per district invited to participate in the study was in proportion to each district's population size.

All *Puskesmas* in Yogyakarta had received International Organisation for Standardization (ISO) Certification, so that data collection points within routine patient flow procedures could be embedded.

3.3.6 Randomisation and blinding

Clusters (*Puskesmas*) were randomised (in a ratio of 1:1) to either treatment arm. Randomisation into the adapted WHO mhGAP arm was done by the Ministry of Health, while randomisation into the Specialist arm was done by our External Statistical Adviser, Dr Chiara Bonetto. Within the study design, the unit of randomisation was the *Puskesmas*, and the unit of observation and analysis was the service user. The cluster model allowed service providers to adhere as a 'whole service' to the treatment method they were trained to provide.

The clustered nature of the study allowed patient-participants to be blinded to the treatment allocation. Outcome assessments were conducted during home visits, and by a different assessor (trained research assistant) blinded to treatment allocation.

3.3.7 Site recruitment

Training dates, logistics, and written support from the Ministry of Health, Provincial Health Authority, and District Health Authorities facilitated the recruitment of all 14 sites to the trial. For the Specialist arm, 14 randomly chosen *Puskesmas* with existing clinical psychologist co-location were recruited. Letters of approval to conduct research by the Ministry of Health and the Provincial Health Authority were sent to all 28 *Puskesmas*, along with an information pack about the trial. A one-day briefing was held with Heads of *Puskesmas*, all clinicians involved, and representatives of District Health Authority, hosted and organised by the Provincial Health Authority. Each *Puskesmas* was assigned a unique cluster number.

All clinicians were current treatment providers in *Puskesmas* and were employees of the District Health Authorities. Therefore, they were not hired specifically for the study, rather the study was integrated into their work. Following a discussion with the Head of Medical Services of the Province in 2016, to ensure that screening and treatment procedures introduced during the trial continue to be integrated as standard operating procedures in each *Puskesmas*, clinicians were not paid to participate in the trial.

It was anticipated that clinicians would fear being pitted against each other, as the trial sought to compare clinical and cost-effectiveness. Three strategies were used to foster cooperation. Firstly, clinicians were introduced to the idea of non-inferiority trial. Secondly, rather than using primary

measures such as diagnostic accuracy, discharge rates, and length of treatment, 'proxy measures' such as symptom reduction at six months, as well as overall health and social functioning (primary outcome measure) reduced the spotlight on individual clinicians. Thirdly, conducting joint training sessions where clinicians got to know each other and ate together, fostered a collegiate atmosphere and the idea that everyone works towards a common goal.

3.3.8 Patient recruitment

Participants were adult primary care attendees visiting any of the 28 *Puskesmas* during the recruitment period, and not currently on any psychosocial or pharmacological therapy for mental health issues, who met the screening criteria (GHQ-12 score of 2 or above, GHQ scoring method 0-0-1-1) (Goldberg and Williams, 2000). Primary care attendees who self-referred to the psychology service were invited to participate if they did not have ongoing treatment for mental health issues. Those receiving ongoing treatment for mental health issues were excluded from participating in the trial.

During the recruitment period, all adult primary care patients in participating clusters (estimated at 40 patients per day) were given the screening questionnaire, the General Health Questionnaire (GHQ-12) (Goldberg and Williams, 2000), as well as a demographic questionnaire from the Client Service Receipt Inventory (CSRI) by Beecham and Knapp, 2001 (Appendix H). The CSRI is a generic questionnaire that records demographics information and health services utility within a specific period (e.g. six months) (Beecham and Knapp, 2001). Participants were given the screening questionnaire at the registration counter, when they obtained a queue number, to be self-completed while waiting for routine blood pressure test.

Primary care patients were given the screening questionnaire at the registration counter, when they obtained a queue number, to be self-completed while waiting for routine blood pressure test. Research assistants trained in scoring the GHQ identified patients who met the screening criteria. To ensure avoidance of any sense of coercion, participants were asked to provide written informed consent before meeting a clinician and were also reassured that declining would not affect usual medical care. Participants were invited to ask questions for clarification. Research assistants double-checked potential participants' understanding of the follow-up requirements and their rights to withdraw. Research assistants provided a brief overview of the trial and an information sheet (Appendix I). Full consent with signature was requested from those who agreed to take part (Appendix J). Participants were then given a questionnaire booklet (Appendix K) to complete while waiting to meet either the *Puskesmas* doctor or psychologist, depending on which cluster they were at (Appendix B). The questionnaire booklet (Appendix K) contained the self-complete version of the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) (Sousa et al., 2010) and the European Quality of Life Scale (EQ-5D-3L) (Oppe et al., 2007). Participants were also informed that they were free to withdraw at any time during the study.

There were procedures in place to assist illiterate patients, which were not required during the recruitment period of this trial. For these patients, consent form would have required the participant's thumbprint and the signature of a witness. Illiterate patients would have been described the research aims and procedures as usual, but rather than self-completing the questionnaire booklet (Appendix K), a research assistant would interview them, completing the booklet alongside.

In the WHO mhGAP treatment arm, participants' medical records and questionnaire booklets were passed to the *Puskesmas* doctor who had received the adapted WHO mhGAP training from the Ministry of Health. Standard medical consultations took place, followed by a structured interview comprising the CIS-R and HoNOS, located in the second half of the questionnaire booklet (Appendix I). *Puskesmas* doctors would then record participants' names, the medical record number, and contact phone number or home address separately. Plans for medications and/or psychosocial therapy, if deemed necessary, were developed together with participants and they were asked to return for further therapy sessions.

In the Specialist arm, participants' medical records were passed to a general practitioner along with a request for a referral to a psychologist. Standard medical consultations for any physical ailments took place with general practitioners before participants went to a psychology consultation room for a structured interview with the *Puskesmas* psychologist. The psychologist then completed both the CIS-R and HoNOS, located in the second half of the questionnaire booklet (Appendix I). Psychologists would then record separately participants' names, the medical record number, and contact phone number or home address. If therapy was deemed necessary, participants were asked to return for further therapy sessions.

The questionnaire booklet (Appendix K) incorporated a section where the clinician could indicate participant's diagnosis at the end of the in-depth interview. This diagnosis was not determined by the CIS-R score, but rather was based on the clinical judgment of each Puskesmas doctor or clinical psychologist. This diagnosis determines whether participants were asked to return for intervention sessions.

3.3.9 Follow-up assessment

Trained and vetted research assistants blinded to treatment arm allocation conducted follow-up at six months. They obtained participants' contact details from their *Puskesmas* and contacted participants via telephone from the *Puskesmas* approximately a month to a fortnight before follow-up home visit. Participant personal details including phone numbers were not shared with other members of the research team and were kept confidential by each field researcher. Participants were re-assessed using the full battery of instruments. At this point, no additional/replacement diagnosis was assigned to the participants.

Prior to the home-visits taking place, all field researchers met the PhD researcher to go through mitigation strategies in the event of a crisis (e.g. if a participant becomes distressed or threatening). Follow-up interviews were conducted without any other persons present. To ensure safety for both the researchers and participants, the room must be unlocked. Field researcher's vehicle (moped) was required to remain parked outside the property of the participant, and the personal properties of field researchers must remain with them at all times. They were required to have a mobile phone, fully charged, and able to make emergency phone calls if required during the home visit. A representative from the *Puskesmas* must accompany field researchers during the home visit.

Participants were re-assessed using the full battery of instruments: WHODAS 2.0 (self-report), EQ-5D (self-report), CIS-R (during the clinical interview), and HoNOS (post-clinical interview). At this point, no additional/replacement diagnosis was assigned to the participants.

The schedule of enrolment, interventions, and assessments is shown in Table 8, based on the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (Chan et al., 2013).

	STUDY PERIOD						
	Allocation	Enrolment	Post-enr	olment	Close-out		
TIMEPOINT**	- t 1	0	t1	t2	etc.	t _x	
RANDOMISATION of Clusters	X						
ENROLMENT:							
Eligibility screen		Х					
Informed consent		Х					
Baseline Interview		Х					
Diagnosis		Х					
INTERVENTIONS:							
WHO mhGAP			←		↓		
Clinical Psychology			-				
ASSESSMENTS:							
CIS-R		X				Х	
HoNOS		Х				Х	
WHO mhGAP		Х				Х	
EQ-5D-3L		X				Х	
Health Services Use		Х				Х	

Table 8. Modified SPIRIT Checklist

3.3.10 Measures

3.3.10.1 Screening

The twelve-item General Health Questionnaire (GHQ-12) was developed to screen for general (nonpsychotic) psychological morbidity among primary care patients (Goldberg & Williams, 1988). Items on the GHQ-12 are rated on a 4-point scale using a time-frame of 'in the last two weeks'. There are two ways of scoring the GHQ-12: the bimodal GHQ scoring method (0-0-1-1) recommended by the test authors for use in clinical settings; and the Likert scoring method (0-1-2-3) which is commonly used in research settings. As this 'real life' study took place in a clinical setting, the bimodal scoring method was used, and patients with score 2 and above were invited to participate in the study.

The screening questionnaire incorporates questions on demographic information such as gender, education, employment, living arrangement, and chronic illnesses based on the Client Service Receipt Inventory (CSRI). The CSRI by Beecham and Knapp (2001) is a generic questionnaire that records demographics information and health services utility within a specific period (e.g. 6 months). Data

collected from the CSRI indicated the number of outpatient visits to *Puskesmas*, inpatient stay, and visits to the emergency (Beecham and Knapp, 2001). Depression and anxiety have been found to increase the risk for hypertension (Meng et al., 2012, Ginty et al., 2013). There is also a strong evidence that depression is a risk factor for diabetes mellitus (Clarke and Currie, 2009). The screening questionnaire is in Appendix H.

3.3.10.2 Primary Outcome Measure

The Health of the Nation Outcome Scale (HoNOS) (Wing et al., 1996) is a 12-item scale to rate mental health service users in various aspects of mental and social health, each on a scale of 0-4. The items are: Overactive, aggressive, disruptive or agitated behaviour; Non-accidental self-injury; Problem drinking or drug-taking; Cognitive problems; Physical illness or disability problems; Problems associated with hallucinations and delusions; Problems with depressed mood; Other mental and behavioural problems; Problems with relationships; Problems with activities of daily living; Problems with living conditions; and Problems with occupation and activities. The ratings were made once all the information became available through clinical interview and took less than 5 minutes for the clinician to complete. HoNOS Total Score is a sum of individual item scores, with higher scores indicating greater mental or social health problems.

The primary outcomes were changes from baseline to the 6-month follow-up assessment in the health and social functioning of participants, as measured by the Health of the Nation Outcome Scale (HoNOS) (Wing et al., 1996).

3.3.10.3 Secondary Outcome Measures

WHO Disability Assessment Schedule (WHODAS 2.0) is a generic assessment instrument for health and disability used across all diseases, including mental, neurological, and addictive disorders. The WHODAS 2.0 covers six domains of functioning, including Cognition; Mobility; Self-care; Getting along; Life activities; and Participation. This trial used the 36-item, self-administered version, taking approximately 20 minutes for self-completion. This trial used the complex scoring method based on item response theory, as advised by the WHO. It took the coding for each item separately and then used an algorithm to determine the Total score by differentially weighting the items and the levels of severity. Total scores are in a metric ranging from 0 (no disability) to 100 (full disability).

The 3-level European Quality of Life Scale (EQ-5D-3L) is a standardised self-report measure of healthrelated quality of life which takes approximately 5 minutes to complete. It comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, with each dimension recording responses at one of three levels: no problems, some problems, and extreme problems (Lewis and Pelosi, 1990). EQ-5D-3L ratings are commonly converted into composite utility scores using country-specific value sets, which measure people's preferences in relation to health and weight each of the levels in each EQ-5D-3L dimension accordingly. The single utility scores represent the state of health-related quality of life for a person at any given time. While the Indonesian value set for the 5level version of the measure (EQ-5D-5L) has been published in 2016, there is no existing value set for EQ-5D-3L.

Existing Thai and Malaysian value sets were found to be the closest alternative. The Thai value set uses the Time Trade-Off (TTO) method to estimate its valuation (Tongsiri and Cairns, 2011), and the Malaysian value set combines both the TTO and Visual Analogue Scale using linear additive regression (Yusof et al., 2012). Both value sets include the N3 model from the original UK Measure and Valuation in Health study. The N3 model adds an interaction variable to capture the effect of any dimension with severe health state.

The Thai value set for the EQ-5D-3L is:

Thai score = 1 - 0.202 - (0.121*mo) - (0.121*sc) - (0.059*ua) - (0.072*pd) - (0.032*ad) - (0.190*m2) - (0.065*p2) - (0.046*a2) - (0.139*N3),

where **mo** is mobility, **sc** is self-care, **ua** is usual activities, **pd** is pain and discomfort, and **ad** is anxiety and depression. Variable **mo** is 1 if mobility is level 2, 2 if mobility is level 3, and 0 otherwise; variable **sc** is 1 if self-care is level 2, 2 if self-care is level 3, 0 otherwise; **ua** is 1 if usual activities is level 2, 2 if usual activities is level 3, 0 otherwise; **pd** is 1 if pain and discomfort is 2, 2 if pain and discomfort is 3, 0 otherwise; **ad** is 1 if anxiety and depression is 2, 2 if anxiety and depression is 3, 0 otherwise. Variable **m2** is 1 if mobility is level 3 and 0 otherwise; **p2** is 1 if pain and discomfort is level 3 and 0 otherwise; **a2** is 1 if anxiety and depression is level 3 and 0 otherwise and; **N3** is 1 if any dimension is level 3 and 0 otherwise.

Where the Malaysian Value set for the EQ=5D-3L is:

 $\begin{aligned} \text{Malaysian score} &= 1 - (0.067*\text{N2}) - (0.116*\text{N3}) - (0.084*\text{m1}) - (0.191*\text{m2}) - (0.097*\text{sc1}) - (0.16*\text{sc2}) \\ &- (0.053*\text{ua1}) - (0.122*\text{ua2}) - (0.054*\text{pd1}) - (0.127*\text{pd2}) - (0.081*\text{ad1}) - (0.086*\text{ad2}) \end{aligned}$

where **mo** is mobility, **sc** is self-care, **ua** is usual activities, **pd** is pain and discomfort, and **ad** is anxiety and depression. Variable **m1** is 1 if mobility is level 2, and 0 otherwise; **m2** is 1 if mobility is level 3, and 0 otherwise; **sc1** is 1 if self-care is level 2, 0 otherwise; **sc2** is 1 if self-care is level 3, 0 otherwise; **ua1** is 1 if usual activities is level 2, 0 otherwise; **ua2** is 1 if usual activities is level 3, 0 otherwise; **pd1** is 1 if pain and discomfort is 2, 0 otherwise; **pd2** is 1 if pain and discomfort is 3, 0 otherwise; **ad1** is 1 if anxiety and depression is 2, 0 otherwise; **ad2** is 1 if anxiety and depression is 3, 0 otherwise. Variable **N2** is 1 if any dimension is level 2 and 0 otherwise and; **N3** is 1 if any dimension is level 3 and 0 otherwise.

Converting EQ-5D-3L scores to both Thai and Malaysian economic values enabled outcome assessors to perform some quick comparisons for consistency of reporting. In the economic analyses of QALY,

it was determined that the Malaysian value sets would be more appropriate for the Indonesian population, given the shared culture, predominant religion, and language of both countries.

For the evaluation of psychiatric morbidity, the clinician conducted a structured interview using the Revised Clinical Interview Schedule (CIS-R) (Lewis and Pelosi, 1990). The CIS-R is a fully structured diagnostic instrument that was developed from an existing instrument, the Clinical Interview Schedule (CIS), initially designed for the use of clinically experienced interviewers. The CIS was revised and developed into a fully structured interview to increase standardisation and to make it suitable to be used by trained lay interviewers in assessing minor psychiatric morbidity in the community, general hospital, occupational and primary care research. As the CIS-R specifically diagnoses mood and anxiety disorders, participants with an indication of other disorders (psychosis, sleep disorders, dementia) were asked additional questions which enabled the interviewers (clinicians) to establish an ICD-10 diagnosis.

For this trial, structured interview using the CIS-R was conducted by general practitioners or clinical psychologists in all participating *Puskesmas*. ICD-10 is widely used in the Indonesian mental health services as the national guideline for the diagnosis of psychiatric disorders (Pedoman Panduan Diagnosa Gangguan Jiwa) is the translated version of ICD-10.

Clinician's own diagnosis of each patient was recorded in participant's interview booklet. While aided by the CIS-R interview questions to make a diagnosis, clinicians formed a diagnosis independently of CIS-R score. During the trial, clinicians were not provided the CIS-R diagnosis for their patients, which was based on its scoring algorithm. The CIS-R scoring took place during the data analysis.

The CIS-R (Lewis et al., 1992) was used to assess the presence of symptoms of common mental disorders. In the CIS-R, there are 14 different symptom groups which participants were asked to consider, regarding the last month prior to the interview, focusing on symptoms experienced within the last week. The 14 symptoms enquired after were: (1) Somatic symptoms; (2) Fatigue; (3) Sleep problems; (4) Irritability; (5) Physical health worries; (6) Depression; (7) Depressive ideas; (8) Worry; (9) Anxiety; (10) Phobias; (11) Panic; (12) Compulsive behaviours; (13) Obsessive thoughts; (14) Forgetfulness/concentration problems. Scores on each symptom group ranged from 0 to 4 (and 0 to 5 for depressive ideas), and Total CIS-R Scores are the sum of each symptom group with higher scores indicating higher levels of symptomatology.

The following were secondary outcomes:

- 1. Changes from baseline to the 6-month follow-up assessment in the disability of participants, as measured by WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) (Sousa et al., 2010).
- 2. Quality-adjusted life year at 6-month follow-up, as computed using the European Quality of Life Scale (EQ-5D-3L) (Oppe et al., 2007).

Attempts were made to collect reasons for treatment discontinuation and loss to follow-up.

3.3.11 Translation and Back-translation

The GHQ-12, HoNOS, WHODAS 2.0, and EQ-5D in Bahasa Indonesia existed prior to the conception of this trial. The Bahasa Indonesia version of the GHQ-12, HoNOS, and WHODAS 2.0 were obtained from the National Institute of Health Research and Development, Ministry of Health, Indonesia. The Bahasa Indonesia version of the EQ-5D was obtained from the Euroqol Group. The CIS-R was translated into Bahasa Indonesia by Ms Wulansari Ardianingsih, MPhil (*Cantab*), MPsi (*UIndonesia*), and back-translated into English by the PhD Researcher.

3.3.12 Researcher training

I distributed open recruitment flyers for research assistants, around Universitas Gadjah Mada campus and through social media groups. I invited 30% of applicants to an interview and recruited 28 research assistants (approximately 10% of all applicants) for the substantive study. Given the tremendous amount of interest, research assistants were selected based on a balance of high educational qualification with people skills and arithmetic ability, filtering in mainly recent medical graduates and social science master degree holders.

I recruited and trained 28 research assistants for the pilot study, and again for the substantive study, to distribute and score the screening questionnaires (GHQ-12) to all adult patients at our research sites. Research assistants were introduced to the background and aims of the research project, as well as detailed screening procedures. They were given a detailed flowchart of the procedure both hardcopy and digitally. They were also informed of the random audits which would be conducted during the period of the project.

For the substantive study, two research assistants were placed on duty per *Puskesmas*. Each dyad consists of a junior doctor and either a medical student or registered nurse. The data collection period coincided with the period where recent medical graduates in Yogyakarta and surrounding areas wait for news of their residency placements, leaving many free to take part as research assistants for our project.

3.3.13 Sample size calculation

First, the sample size for non-inferiority individual randomisation RCT is calculated as a reference, using the estimated mean total HoNOS rating as a primary outcome (Wing et al., 1996). The formula used is by Zhong, (2009). Assuming statistical significance value (α) of 0.05 and statistical power of 0.80, the standard deviation of 5.2, and clinical significance threshold (δ 0) of 2 (Audin et al., 2001), the minimum sample size required for an RCT is 84. The standard deviation of 5.21 and clinical significance threshold used is the only available data on HoNOS reported from a sample of patients from eight National Health Service outpatient and community psychotherapy services in England. Total HoNOS scores range between 0 and 48, and a clinical significance threshold (δ_0) of 2 could represent a

plausible and realistic intervention effect. The minimum sample size using these estimates with a statistical bilateral significance value (α) of 0.05 and a statistical power of 0.80 is 84.

A larger sample size was needed to compensate for the clustering effect. For a trial with a fixed number of equal sized clusters (k), the required sample size per arm is n_c, such that (Hemming et al., 2011):

$$\mathbf{n}_{\rm c} = \frac{n_i k [1-\rho]}{[k-n_i \rho]}$$

where n_i is the sample size required under individual randomisation and ρ is the intra-cluster correlation coefficient (ICC). The cluster randomisation might result in reduced efficiency and loss of power because the within-cluster responses tend to be more similar than those of individuals from different clusters (commonalities in the selection, exposure, shared environment, mutual interaction). A larger sample size was therefore needed to compensate for this clustering effect. Our approach is simplified because it does not consider variations in the number of participants in each cluster. Although this type of imbalance in cluster size may reduce the power of the trial, the loss is negligible for studies with more than 100 patients per arm (Guittet et al., 2006). Based on the additional assumption of an ICC of 0.1, the number of patients required would be 189 in each arm. Implementation research studies showed that in medical settings ICCs for outcome variables were generally lower than 0.05 (Campbell et al., 2005). In our trial, I decided to assume a high value for the ICC to consider a possible wide variation across different *Puskesmas*.

With an attrition rate of approximately 20%, I expected that a sample size of about 227 patients per arm (approximately 16 for each *Puskesmas*) should yield sufficient power.

Following the completion of baseline recruitment, a more accurate estimate of ICC can be calculated using the formula from Dr Yannan Jiang, University of Auckland. The formula (Jiang, 2012) required a one-way analysis of variance, where the dependent variable is total HoNOS score, and the grouping variable is the cluster (*Puskesmas*).

$$ICC = \frac{(Between Groups Means Square - Within Group Means Square)}{(Between Groups Means Square + (number of participants per cluster - 1))}$$

Given the new ICC derived from the trial dataset, the required sample size to keep a statistical power of 0.80 and a statistical bilateral significance value of 0.05 can be re-calculated.

3.4 Analysis

3.4.1 Intervention Uptake

Participant engagement with the treatment process was summarised and reported descriptively. There was no consensus regarding the appropriate number of therapy follow-ups (dose).

3.4.2 Analysis of primary and clinical outcome measures

These analyses were carried out using the STATA software package, version 13. Cleaning of outcome and baseline data was conducted without the treatment group allocations in view. Summary statistics from these preliminary analyses were reviewed to identify data errors.

Preliminary analyses compared the characteristics of participants with and without complete data at sixmonths follow-up, by treatment group. They were carried out for the primary and secondary outcomes. This analysis was used to develop an understanding of the missing data mechanism and to determine the appropriate methods for dealing with missing outcome data.

Subsequent analyses took place with the valuable inputs and guidance of Senior Statistician at the University of Verona and External Advisor/Trial Manager for the PhD, Dr Chiara Bonetto. The substantive study is a pragmatic cluster randomised controlled non-inferiority trial with the aim to assess the clinical effectiveness of two frameworks of primary mental health service provision in *Puskesmas* (community health centres) within a province, Yogyakarta. The unit of randomisation was the *Puskesmas* unit, and the unit of observation and analysis was the service users. The objective of conducting a non-inferiority trial was to demonstrate that neither the WHO mhGAP framework nor the Specialist framework was worse than the other with regards to clinical outcomes such as symptom severity and wellbeing.

Analyses were conducted using an intention-to-treat (ITT) approach. The effect of the type of service on HoNOS, EQ-5D and WHODAS 2.0 scores at six months were analysed separately in mixed-effects random regression models. Considering the trial design, in which patients (level 1) were nested within *Puskesmas* (level 2) [refer to the CONSORT guidelines for cluster randomised trials], the individual *Puskesmas* were included in the models as a random effect. Each model included treatment allocation and the baseline score of the outcome investigated as fixed effects.

In a secondary analysis, any missing data on follow-up outcomes were estimated using a multiple imputation approach by chained equations (MICE), which generated several different plausible imputed data sets and combined results from each of them. The predictive mean matching would be used to deal with possible non-normality when imputing continuous variables.

3.4.3 Economic Evaluation

3.4.3.1 Perspective

The primary perspective of the economic evaluation was the Health Systems perspective, in line with the preference of NICE guidelines (Drummond, 2016) and in line with the effort from national and provincial governments to provide universal health coverage to citizens. This study included only the use of mental health resources including *Puskesmas* follow-up services. While data on overnight

hospitalisation and visits to outpatient general medical care were captured, they were not included in the analysis as they were not related to participants' mental health.

At the follow-up, participants were asked to recall their use of health resources during the trial period (6 months). Differences in use of services between trial arms were compared and are reported for each service as the proportion of the group who had at least one contact. Statistical comparisons were not made to avoid problems of multiple testing and to keep the focus of the evaluation on costs and cost-effectiveness.

3.4.3.2 Costs

For each participant, a nationally applicable unit cost was applied to each item of service use reported during the trial (at the follow-up interview), to calculate the total cost for the duration of the trial. All costs are reported in Rupiah at 2017 prices. Discounting was not relevant as the follow-up did not exceed 12 months. Unit costs for primary care outpatient and inpatient services were obtained from a provincial cost calculation conducted in 2012 and adjusted for inflation based on national inflation rates https://www.statista.com/statistics/320156/inflation-rate-in-indonesia.

This trial used Yogyakarta health services unit cost valuation from Fidiyawati (2013) which followed the methodology recommended by the Directorate of Community Health Service Insurance, Ministry of Health 2003. This study of 2012 values (though published in 2013) indicated that the average unit cost in Yogyakarta outpatient medical service was Rp 13,961 and inpatient Rp 93,052 (\pounds 1 ~ Rp 19000 in March 2018). Based on these 2012 valuations (Fidiyawati, 2013), the 2016 and 2017 values could be calculated by taking into account published inflation rates as displayed in Table 9 (Statista, 2018).

In the absence of empirical data, the crude unit cost of Clinical Psychology consultation in *Puskesmas* could only be estimated. Psychologists' monthly pay set by the provincial government (Rp 3,000,000 effective January 2017) was divided by the average number of psychology consultations per month (231 appointments in 2017; annual average of 2772 appointments per psychologist), the unit cost for psychology consultation is estimated to be Rp 12, 987. The cost to health services of each psychology consultation takes into account the retribution for infrastructure, ancillary workforce, and medical record administration, which in Yogyakarta is determined at Rp 2100 (Widodo, 2016). The total cost of clinical psychology consultation in 2017 is Rp 15,087 per appointment (Table 9).

To receive free psychological care, participants required a GP referral. For participants in the Specialist Arm, the cost at baseline is a composite of the cost of GP consultation (which includes retribution) and the unit cost of psychology consultation (without retribution) which amounts to Rp 30,468.

Table 9. Unit costs of Puskesmas Mental Health Services, considering published inflation rates

YEAR INFLATION WHO mhGAP Consultation COST	Clinical Psychology Consultation
RATE in Rupiah	COST in Rupiah

2012	3.98%	13961	
2013	6.41%	14516	
2014	6.40%	15447	
2015	6.36%	16435	
2016 (Baseline)	3.53%	17481	Without retribution: 12987
2017 (Follow-up)	4.02%	18098	15097

3.4.3.3 Analyses

The primary economic evaluation explored cost-effectiveness in terms of HoNOS, the primary outcome for the trial. A secondary cost-utility analysis explored effectiveness in terms of Quality-Adjusted Life Years (QALYs).

EQ-5D-3L utility scores were used to calculate QALY improvements during the period of the trial (6 months) using the area under the curve approach (Manca et al., 2005) and this formula:

$$QALY Improvement = \frac{QALY_{T0} + QALY_{T1}}{2} \times \frac{1}{2} years$$

Incremental cost-effectiveness ratios (ICERS), i.e. the additional cost of one intervention compared with another divided by the additional effect, were calculated based on parameter estimates from random-effects linear regression models that represent costs and both outcomes and take into account the clustered structure of these data. While the ICER allows costs and outcomes to be considered together in a decision-making context, it is calculated from four sample mean values and is therefore subject to statistical uncertainty. The uncertainty of these estimates was explored first, by bootstrapping 1000 resamples to generate a new distribution of estimates and plotting these onto a cost-effectiveness plane for interpretation and then, by constructing cost-effectiveness acceptability curves (CEAC). The CEAC is a plot of the probability of the intervention being cost-effective (y-axis) for a range of willingness to pay thresholds per unit improvement in outcome (x-axis) (Fenwick et al., 2001). Initially, for the cost-utility analysis the WHO recommendation of three times GDP per capita (Rachapelle et al., 2013, Eichler et al., 2004) or a calculation based on estimates of opportunity costs (Woods et al., 2016) were considered to approximate an Indonesian willingness-to-pay threshold, but recent research on the Indonesian willingness-to-pay threshold for medical intervention enabled a more exact analysis to be conducted (Kristina et al., 2017).

3.5 Cultural Challenges and Bias

Prior to the trial, I applied for Leave to Work Away from the University of Cambridge, in light of the fieldwork and visiting fellowship to be undertaken in Indonesia. As part of the application, I completed

a Risk Assessment document, which helped me highlight several potential issues at the fieldwork location.

While I am an Indonesian, I had not lived in the country for 16 years prior to my first fieldwork visit to Yogyakarta. During my first fieldwork, there was a terrorist attack in Jakarta, where several terrorists bombed and shot at places and people with foreign attributes, e.g. Starbucks. I established a regular reporting schedule with my Supervisor and Adviser in Cambridge, to ensure that safety issues could be immediately dealt with, and if required, a return to Cambridge arranged. Having to travel accompanied, part of my Risk Assessment compromise, would also limit my independence to travel between each fieldwork site, given the distance and remote location of many sites (up to four hours from the centre of Yogyakarta).

I was aware of my negatively perceived identity as a double minority in Indonesia: both in ethnicity and religion. As a non-medical doctor, I was also at the lower end of the social power when compared to my stakeholders: Muslim, Javanese, older medical doctors working as civil servants. Despite my Cambridge affiliation, I did not enjoy the "White Privilege" granted to lighter-skinned researchers when working in less developed context, such as the privileges granted to Japanese Dr Nozomi Sakata when conducting research in Tanzania (Naveed et al., 2017). Conversely, as a woman ethnic Chinese Indonesian researcher who does not wear a hijab, I was vulnerable to discrimination at my fieldwork sites. Since I could not show respect by speaking High Javanese, I knew I had to be especially mindful of my attire and body language when interacting with stakeholders. Greeting older and important stakeholders, I bowed and touched my forehead to the back of their right hand. Towards my research assistants, I had to balance authority with Javanese politeness, aware of the secondary status of a woman in Javanese culture (Smith-Hefner, 1988).

I was also aware of the rent-seeking culture of the fieldwork location, which could potentially present ethical challenges related to bribery requests, as I represented a foreign university. Prior to each data collection period, I would have to renew the provincial and district research licenses in person, as well as renew stakeholders' support for the project. In my role as permission seeker, stakeholders who acted as gatekeepers could potentially present challenges. In light of these potential challenges, I developed local collaborations and formed a fieldwork advisory team, spearheaded by the previous Dean of Universitas Gadjah Mada Faculty of Medicine (Professor Trisnantoro) and the current Director of the Centre for Public Mental Health (Dr Setiyawati). Professor Trisnantoro is a respected figure in the medical community in Yogyakarta, and on the other hand, all Puskesmas psychologists were required to submit biannual reports to Dr Setiyawati. Their presence in the advisory team was deemed helpful should issues arise locally during fieldwork.

As a trained psychologist, there was also a potential that I had implicit bias, favouring the Specialist treatment arm over the WHO mhGAP treatment arm. Implicit bias generally tends to favour our own

ingroup, and could influence the way I conducted training, negotiation with clinicians, my assessment of treatment outcomes, and/or recommendations at the end of the trial. I ensured that all trainings prior to the pilot and substantive trials were conducted together for both *Puskesmas* doctors and psychologists. To avoid clinicians feeling as though they were pitted against each other, representatives from the Provincial Health Authority opened the training sessions and provided a closing address. While I orchestrated the follow-up effort, research assistants who were Javanese collected patient outcomes data, introducing themselves in High Javanese as an expression of respect. The Trial Manager (Dr Bonetto) was an independent party who conducted the randomisation of clusters, supervised the data analysis, and performed the ITT analysis. Being aware of potential biases, and taking the above steps as countermeasure, I hope to present an objective evaluation of the two treatment frameworks.

3.6 Trial administration

This trial took place under the supervision of an advisory team which comprises of:

- 1. Supervisor, Dr Tine Van Bortel (University of Cambridge),
- 2. Adviser, Prof Carol Brayne (University of Cambridge), and
- 3. Statistical Adviser/Trial Manager, Dr Chiara Bonetto (University of Verona).

In addition, this trial received ground support from fieldwork advisory team at Universitas Gadjah Mada, at which I was appointed Visiting Fellow, including:

- 1. External Supervisor, Dr Diana Setiyawati (Centre for Public Mental Health),
- 2. External Adviser, Dr Bambang Hastha Yoga (Department of Psychiatry)
- 3. External Adviser, Prof Laksono Trisnantoro (Centre for Health Policy), and
- 4. External Adviser, Dr Yodi Mahendradhata (Faculty of Medicine).

4 TRIAL RESULTS

Having established the unanswered questions to be addressed in the roll-out of internationally encouraged approaches to primary mental health care (Chapter 1), and having detailed the methodology to utilise the unique opportunity to evaluate different approaches in specific areas within Yogyakarta, I have four phases from which results were produced. These had the following objectives:

- Phase 1 (December 2015 February 2016): Field observations, understanding patient flow within research sites and their socio-cultural contexts. These observations form the basis for Chapter 3 and are described in the context of Site Recruitment below.
- Phase 2 (May June 2016): Pilot study described in Chapter 3.
- Phase 3 (December 2016): Recruitment period for substantive study.
- Phase 4 (June July 2017): Follow-up assessment.

This chapter begins with details of Phase 1 before focusing on Phases 3 and 4, providing the results of the substantive study. The site recruitment, then the clinicians involved are described. Patient recruitment is described next with a CONSORT diagram showing the flow of participants through the different stages of the trial (Figure 10).

Participants' demographic and clinical characteristics with a description of those demographic variables related to participants' outcomes can be found in Table 10. The characteristics of participants who left the trial (drop-outs) are afterwards shown (Tables 13-14).

The clinical effectiveness of the two treatment arms: the adapted WHO mhGAP arm and the Specialist Arm are presented subsequently with demographics captured at baseline, before interventions described in detail in the previous Chapter (trial protocol). Comparisons of the two treatment arms in both the primary outcome (HoNOS) and secondary outcomes (EQ5D and WHODAS 2.0) are also presented. The ITT analysis following the research protocol described in Chapter 3 was conducted by Dr Chiara Bonetto as Trial Manager, per international recommendations to safeguard the quality of the trial.

Cost-effectiveness analyses were conducted on the HoNOS, comparing the cost of improvement in each "unit" of health. This chapter further describes the analysis of the cost-utility of both treatment arms, using the EQ5D data at baseline and follow-up, converted into quality of life utility scores then QALY.

4.1 Site Recruitment

The first fieldwork in Yogyakarta, Indonesia, took place between December 2015 and February 2016 with the main purpose to observe the primary health care system and the provision of mental health services within it. I began a one-year appointment as a Visiting Fellow at the Centre for Public Mental Health (Universitas Gadjah Mada) in January 2016.

Key observations of state-run primary care clinics:

- 1. Clinics were open all weekdays and Saturdays in the morning, and a few are also open for some hours in the early evening.
- 2. All *Puskesmas* in the province had undergone an ISO accreditation which requires a specific patient flow in each *Puskesmas*. Patients pick-up a queue number upon arrival, either for general medical services, dental services, psychology services, or child vaccination services. Patients attending general medical services or dental services have their blood pressure measured routinely.
- 3. Some *Puskesmas* in Yogyakarta have basic inpatient facilities as well as isolation rooms for the containment of suspected cases of infectious diseases. Additionally, some *Puskesmas* in Yogyakarta have their own ambulances, with the licence to operate within the catchment area of the *Puskesmas*.
- 4. Medical and dental services are provided free of charge for patients living within the catchment area of the *Puskesmas*. Patients from outside the catchment area, but from within the district, pay a nominal consultation fee of Rp. 7000 (~ £0.35) per visit. Patients from outside the district pay a higher consultation fee of Rp. 14000 (~ £0.70).
- 5. Patients requiring psychology services can either get a referral from general medical services (in which case they get a quota of 6 appointments free of charge for the year) or go directly to psychology services without referral (in which case the fee differs in different districts). In the City District, even patients who attend psychology services without referral can attend free of charge if they are from within the district, and a consultation fee of Rp. 14000 (~ £0.70) for patients outside the district. In the Sleman District, patients who attend psychology services without referral must pay a consultation fee of Rp. 14000 (~ £0.70) for patients outside the district, and a higher consultation fee of Rp. 14000 (~ £0.70) for patients outside the district.
- 6. Most psychologists have three to six appointments per day. Most of their clients are made up of those who attend for pre-marital counselling or pre-Hajj pilgrimage briefing, which is mandatory for residents of Yogyakarta province.
- 7. A new policy was introduced in January 2016 regarding the starting salary of psychologists employed in *Puskesmas* newly set at Rp 3,000,000 (~ £157) per month, including additional support funds. For general practitioners, the starting salary is Rp 3,700,000 (~ £197) per month including support funds.

Following randomisation of *Puskesmas* into both treatment arms, 14 *Puskesmas* received the adapted WHO mhGAP training from the Directorate of Mental Health, and form the WHO mhGAP treatment arm. These clinics were sent an information pack concerning the trial, and general practitioners were directly recruited during the training. The comparator, the Specialist treatment arm, comprises 14 *Puskesmas* which were sent an information pack concerning the trial. Clinical Psychologists were recruited into the project before the start of the Pilot Study.

4.2 Clinicians' Characteristics

Of the 14 general practitioners who took part in the trial, 3 were men while the rest were women. All general practitioners had civil servant status and received their licence to practise from the District government which manages the health budget for the district, including the management of all state-owned *Puskesmas*. All general practitioners were full-time permanent *Puskesmas* doctors, and not on rotation, ensuring they stay within the *Puskesmas* even after the end of the trial period. In comparison, all 14 psychologists who took part in the trial were women. Each *Puskesmas* directly employed psychologists.



Figure 7. Training of clinicians involved in the trial, December 2016

4.3 Patient Recruitment

Trial participants were recruited from among adult primary care attendees at 27 participating *Puskesmas* (all 14 WHO mhGAP arm, and 13 Specialist arm). Recruitment took place between 1-24 December 2016.



Figure 8. Research Assistant reading out the screening questionnaire to a patient

Initially 14 Specialist arm *Puskesmas* were recruited. Following careful discussion with the supervisory team, one *Puskesmas* in the specialist arm had to be dropped from the trial, losing those potential participants. This was because the Head of this *Puskesmas* prevented any psychiatric interview from taking place unless additional monetary benefits for his family were provided which was not part of the original agreements and would have threatened the integrity of the research.



Figure 9. Resisting the Request for Bribes. L-R: The Author; Local Adviser, Dr Bambang Hastha Yoga; Head of Puskesmas B3 which was eventually dropped from the trial.

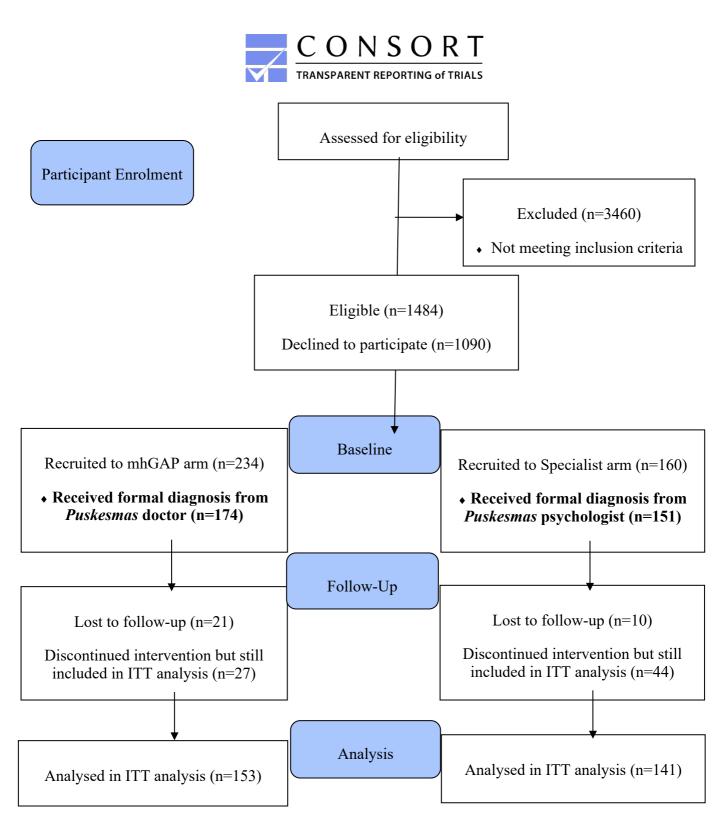


Figure 10. CONSORT 2010 Flow Diagram (Modified)

During the recruitment period, 4944 adult primary care patients attended the general medical clinic at 27 participating *Puskesmas* (CONSORT Diagram, Figure 10). Following screening (n=1484 met the screening criteria) and in-depth psychiatric interview (n=394), 174 WHO mhGAP arm and 151 Specialist arm participants were given a formal diagnosis and recruited into the trial.

4.3.1 Revised Sample Size

The original target sample size was 189 per treatment arm, to account for possible clustering effect and an imbalance in the number of participants per cluster. Although this type of imbalance in cluster size may reduce the power of the trial, the loss is negligible for studies with more than 100 patients per arm (Guittet et al., 2006). Following the completion of the baseline measurements, the required sample size was therefore recalculated with the intra-cluster correlation for the primary outcome (HoNOS) derived from the baseline dataset.

Using the formula described in Chapter 3 (Jiang, 2012), I derived an estimate of intra-cluster correlation of 0.025 from the baseline dataset. Having determined the sample size required for RCT (84 participants, see Chapter 3), the required sample size for the trial was re-calculated prior to follow-up. Using the formula described in Chapter 3 (Hemming et al., 2011), to keep a statistical power of 0.80 and a statistical bilateral significance value of 0.05, the number of required participants per treatment arm, is estimated to be **96**.

4.3.2 Retention

While 325 participants in total were given a confirmed or probable diagnosis, and eligible for intervention, of these, 295 participants could be approached for re-interview at follow-up. Our retention rate is therefore 90.8%.

There was good follow up with more than three quarters attending one or more sessions delivering interventions after baseline (223/295,76%) at a *Puskesmas*. I further assessed if the likelihood for returning for intervention is different among the two treatment arms. The number of participants returning for intervention in the WHO mhGAP arm is significantly more than in the Specialist Arm ($\chi^2 = 7.364$, p=0.007), 82% (n=126) and 69% (n=97) respectively.

4.3.3 Participants Lost to Follow-up

At follow-up, 31 (9.7%) participants dropped out: 21 (12.1%) and 10 (6.8%) in the WHO mhGAP and Specialist arms, respectively (Consort Diagram, Figure 10). Of these, 23 (74.2%) were women and 8 (25.8%) men, of mean age 43.4 (17.5) and median of 46 (30). More than half (n=17, 54.8%) were of low education level, compared to 50% and 32% patients followed up from the WHO mhGAP and Specialist arms respectively. Considerably more participants lost to follow-up were unemployed at baseline (25.8%) compared to 10.3% patients followed-up at both the WHO mhGAP and Specialist

arms. There were no notable differences in clinical characteristics at baseline with those who were followed-up.

Several participants lost from the WHO mhGAP arm were staff members of various *Puskesmas* and declined to participate with the follow-up as they feared disclosure to colleagues. Many participants did not have a current contact number retained at the *Puskesmas*. For these, a check at their primary address was made. This task was made difficult by the lack of consistency in the recorded address, i.e. at times the recorded address detailed the village name, and not a home address. The investigating team had some demographic details of the participants, such as gender, age, and birth location. It was discovered that some participants had relocated away from their recorded address. As such, it was nearly impossible to track their whereabouts. Two participants have moved to West Java and Jakarta respectively and did not attend the follow-up sessions. Five participants from a Specialist Arm *Puskesmas* in Bantul regency were also part of a different research project. It was apparent during our follow-up effort that their medical records had been removed from the *Puskesmas* without the knowledge of the research team although with the permission of the Head of the Puskesmas. These participants could not be traced.

4.4 Patient Characteristics

At baseline, 174 WHO mhGAP arm and 151 Specialist arm participants received a formal diagnosis of psychiatric disorders. These were the participants invited to return for intervention and follow-up assessment six months after recruitment.

All participants attended primary care with complaints of a physical ailment, and therefore all participants are likely to have mental and physical multimorbidity. In other countries, mental and physical multimorbidity was found to be common among older people (van den Brink et al., 2013), and conversely, physical ailments are common among psychiatric patients (Lyketsos et al., 2002). The WHO mhGAP protocol even stated "Depression commonly occurs alongside other MNS conditions as well as physical conditions" (WHO, 2010, WHO, 2016). In the trial, only chronic common conditions, diabetes and hypertension, were recorded.

4.4.1 Demographic Characteristics

The groups did not differ in many socio-demographic characteristics, except for specialist arm patients, who were younger, with a higher educational level and a higher percentage of Indonesian speakers (Table 10).

	WHO mhGAP arm (n=174)	Specialist arm (n=151)	Test and Significance of Difference
Gender, n (%)			
Male	46 (26.4)	44 (29.3)	χ ² =0.34, df=1, p=0.562
Female	128 (73.6)	106 (70.7)	
Age	(3 missing)	(1 missing)	
mean (SD)	44.1 (15.0)	38.5 (14.8)	t=3.35, df=319, p=0.001
median (IQR)	46.0 (23.0)	38.0 (26.0)	
Marital Status, n (%)		(1 missing)	
Unmarried	34 (19.5)	45 (30.0)	χ^2 =4.98, df=2, p=0.083
Married	124 (71.3)	91 (60.7)	
Separated, Divorced, Widowed	16 (9.2)	14 (9.3)	
Language, n (%)		(4 missing)	
Indonesian	16 (9.2)	27 (18.4)	χ ² =9.21, df=2, p=0.010
Javanese (fluent in Indonesian)	142 (81.6)	115 (78.2)	
Javanese (not fluent in Indonesian)	16 (9.2)	5 (3.4)	
Educational Level, n (%)		(1 missing)	
Low (Elementary-Middle School)	86 (49.4)	46 (30.7)	χ^2 =11.74, df=1, p=0.001
High (High School, Diploma, Degree)	88 (50.6)	104 (69.3)	
Living Condition, n (%)	(1 missing)	(2 missing)	
Alone	19 (11.0)	22 (14.8)	χ ² =2.43, df=3, p=0.487
Partner	93 (53.8)	69 (46.3)	
Relatives	21 (12.1)	17 (11.4)	
Parents	40 (23.1)	41 (27.5)	
Working Status, n (%)		(1 missing)	
Employed	84 (48.3)	75 (50.0)	χ ² =0.45, df=2, p=0.800
Unemployed	24 (13.8)	17 (11.3)	-
Housewife, Student, Retired, Volunteer	66 (37.9)	58 (38.7)	

Table 10. Socio-demographics of patients assessed at baseline (n=325).

4.4.2 Clinical Characteristics

No differences were observed in service utilisation in the six months before baseline assessment, with the only exception being outpatient contacts more frequently in the WHO mhGAP arm (Table 11). A sizeable proportion of participants from both treatment arms were diagnosed with Mixed Anxiety and Depression, 25.4% and 37.2% in the WHO mhGAP and Specialist arms respectively.

	WHO mhGAP arm (n=174)	Specialist arm (n=151)	Test and Significance of Difference
Hospital Admissions, n (%)	(1 missing)	(1 missing)	
No	142 (82.1)	133 (88.7)	χ ² =2.75, df=1, p=0.097
Yes	31 (17.9)	17 (11.3)	
Outpatient Contacts, n (%)		(1 missing)	
No	107 (61.5)	108 (72.0)	χ^2 =3.98, df=1, p=0.046
Yes	67 (38.5)	42 (28.0)	
Puskesmas Contacts, n (%)		(1 missing)	
No	42 (24.1)	43 (28.7)	$\chi^2=0.85$, df=1, p=0.355
Yes	132 (75.9)	107 (71.3)	
Diagnosis at Baseline, n (%)			
No Disorder per CIS-R	8 (4.6)	18 (12.2)	
Mild or Moderate Depressive Episode	34 (19.7)	20 (13.5)	
Panic Disorder	17 (9.8)	3 (2.0)	
Obsessive Compulsive Disorder	0 (0.0)	3 (2.0)	
Social Phobia	16 (9.2)	2 (1.4)	
Agora Phobia	0 (0.0)	1 (0.7)	
Specific (Isolated) Phobia	6 (3.5)	2 (1.4)	
Generalized Anxiety Disorder	16 (9.2)	8 (5.4)	
Mixed Anxiety Depression	44 (25.4)	56 (37.2)	
Other Disorder	32 (18.5)	36 (24.3)	

Table 11. Service utilisation in the six months before baseline assessment and CIS-R diagnosis at
baseline (n=325).

Participants' diagnosis at baseline described here are purely based on the algorithm of the CIS-R, rather than the listed diagnosis of each clinician who interviewed the participants. Reporting participants' diagnosis based on the CIS-R here is intended purely to improve objectivity when comparing baseline with outcomes at 6-month follow-up. As the scoring was conducted post-hoc, clinicians were not provided these diagnoses, based on scoring the CIS-R interview, during the trial period. It is noted that some of the diagnoses computed by the algorithm are beyond the scope of the WHO mhGAP framework, but are within the Medical Doctors Competency Standard list of conditions which medical graduates must be familiar with and able to provide initial intervention for, before obtaining a practice license.

Table 12 captures a comparison of participants' means of dependent variables at baseline and followup, as well as a test of significant difference. All total scores (dependent variables) were treated as continuous variables, and a paired samples T-test was performed for each baseline and follow-up pair of scores.

	Baseline	Follow-up	Test and Significance of Difference
CIS-R Total Score			
Overall (n=294)	10.97 (11.47)	4.43 (5.49)	t=9.63, df=293, p=0.000
WHO mhGAP (n=153)	10.08 (12.36)	4.63 (5.73)	t=5.09, df=152, p=0.000
Specialist (n=141)	11.93 (10.37)	4.21 (5.22)	t=9.62, df=140, p=0.000
HoNOS Total Score			
Overall (n=287)	5.45 (5.13)	3.45 (4.49)	t=6.10, df=286, p=0.000
WHO mhGAP (n=150)	4.64 (4.50)	3.40 (4.38)	t=2.66, df=149, p=0.009
Specialist (n=137)	6.34 (5.70)	3.50 (4.62)	t=6.26, df=136, p=0.000
WHODAS 2.0			
Overall (n=294)	23.62 (16.32)	12.41 (13.99)	t=11.56, df=293, p=0.000
WHO mhGAP (n=153)	24.23 (16.89)	12.10 (13.99)	t=8.41, df=152, p=0.000
Specialist (n=141)	22.95 (15.71)	12.77 (14.03)	t=7.98, df=140, p=0.000
EQ-5D Malaysian Value			
Overall (n=295)	0.79 (0.13)	0.83 (0.11)	t=-11.01, df=294, p=0.000
WHO mhGAP (n=153)	0.78 (0.14)	0.83 (0.11)	t=-9.32, df=152, p=0.000
Specialist (n=141)	0.80 (0.13)	0.83 (0.11)	t=-6.31, df=140, p=0.000

Table 12. Means of Dependent	Variables at Ba	aseline and 6-months	Follow-up for participants
who completed the trial			

A statistically significant reduction in mental and social health problems at follow-up was found, as indicated by the HoNOS Total Score, for both treatment arms and overall (Table 12). Internal Consistency of the HoNOS is good, Cronbach's alpha 0.77 at baseline and 0.81 at follow-up.

Internal Consistency of the EQ-5D-3L is poor at baseline, Cronbach's alpha 0.56, but good at followup, Cronbach's alpha 0.73. I found a significant increase in health-related quality of life as measured by the EQ-5D-3L utility index (Malaysian value set, Table 12).

Next, between-*Puskesmas* differences were analysed. Appendix L compares participants' means, standard deviations, median, as well as the range of scores in all dependent variables at baseline and follow-up, arranged by *Puskesmas*. One-way Analyses of Variance were conducted on the absolute change in clinical interview ratings as well as primary and secondary outcome measures (Appendix L). Absolute change is defined as participant score at follow up deducted by the score at baseline. For absolute change in Clinical Interview Ratings, there are significant differences between *Puskesmas* in health and social functioning as measured by the HoNOS, F (26) = 2.76, p<0.001. Statistically significant differences between *Puskesmas* in the reduction of disability as measured by WHODAS 2.0 was also found, F (26) = 2.42, p<0.001). In measuring inter-*Puskesmas* differences in improving Quality

of Life, the Malaysian utility index shows the differences are not statistically significant, F (26) = 0.917, p=0.585.

Gender differences were statistically significant on the absolute change in disability ratings as measured by the WHODAS 2.0, t (291) = -2.083, p<0.05, as well as the Quality of Life utility index as measured by the Malaysian utility index, t (292) = 2.057, p<0.05. Women were found to show a greater reduction in disability and a larger improvement in Quality of Life utility index. They also showed a greater reduction in clinical symptoms and health and social functioning although these differences were not statistically significant.

Marital status was only statistically significant on the absolute change in health and social functioning as measured by the HoNOS, F(2) = 3.615, p<0.05, with those who are separated, divorced or widowed showing a greater improvement in health and social functioning during the trial period. They also showed a greater reduction in clinical symptoms and disability ratings, as well as greater improvement in Quality of Life utility index although these differences are not statistically significant.

Education was only statistically significant on the absolute change in disability ratings as measured by the WHODAS 2.0, t (291) = 2.188, p<0.05, with those educated at the High School level or above showing a greater reduction in disability ratings. There were no significant or meaningful differences in other outcome variables. Employment status, on the other hand, were found to not have any significant influence on any of the outcome variables.

While those living with parents or relatives show greater improvements across all outcome variables, these differences did not reach significance.

Those with diabetes were found to have a statistically significantly greater improvement in clinical symptoms as measured by the CIS-R than those without, t (292) = 2.174, p<0.05. They were also found to have greater improvements in health and social functioning as well as Quality of Life utility indices, but less in disability ratings, compared to those without diabetes. These differences, however, are not statistically significant.

In comparison, those with chronic high blood pressure at baseline were found to have statistically significantly lower improvements in health and social functioning as measured by the HoNOS, t (285) = -2.170, p<0.05, and lower reduction in disability ratings as measured by the WHODAS, t (291) = - 3.073, p<0.05. They also have less reduction in clinical symptoms compared to those without high blood pressure, although this difference is not statistically significant. Those with chronic high blood pressure at baseline were found to have a statistically significantly higher systolic blood pressure at the recruitment interview, t (257) = -11.336, p<0.001. The data did not show significant differences in diastolic blood pressure.

Diagnosis at baseline was found to be statistically significant in influencing improvements in clinical symptoms as measured by the CIS-R, F (4) = 12.094, p<0.001, as well as increases in health and social functioning as measured by the HoNOS, F (4) = 4.019, p<0.05. Those diagnosed with comorbid Anxiety and Depression were found to have the greatest average reductions in clinical symptoms. These participants, along with those diagnosed with other mood disorders at baseline were found to have the greatest average improvements in health and social functioning.

4.4.3 Drop-outs

During the trial period, 31 (9.5%) participants recruited at baseline declined to participate further in the trial or were unreachable due to having moved to a different province. Of these, 21 (67.7%) belonged to the WHO mhGAP arm and 10 (32.3%) belonged to the Specialist arm. Most drop-outs were female (n=23, 74.4%). More than half (n=17, 54.8%) were married, and about half (n=15, 48.4%) were living with their partners. More than half (n=17, 54.8%) were educated below High School (low education), a greater percentage than those who completed the trial.

The following table indicates the frequency of drop-outs by *Puskesmas*. The table below indicates that on top of the expected rate of drop-outs in individual *Puskesmas*. It is alarming that almost half (n=8, 42.1%) of 19 patients recruited at *Puskesmas Ngaglik II* dropped out of the trial. All five drop-outs from *Puskesmas* Wates could not be contacted as the *Puskesmas* lost their medical record files.

In comparison, the MANAS Trial which evaluated mental health interventions by lay counsellors in primary care, in India, had an attrition rate of 12-15% in the two treatment arms (Patel et al., 2010).

	Recruited	Drop-Outs	Percent of Recruited	Percent of All Drop-Outs	Treatment Arm
NGAGLIK II	19	8	42.1	25.8	WHO mhGAP
UMBULHARJO I	14	3	21.4	9.7	WHO mhGAP
KOTA GEDE I	16	3	18.8	9.7	WHO mhGAP
JETIS II	17	1	5.9	3.2	WHO mhGAP
SRANDAKAN	10	1	10.0	3.2	WHO mhGAP
WATES	23	5	21.7	16.1	WHO mhGAP
MINGGIR	9	1	11.1	3.2	Specialist
MLATI II	11	1	9.1	3.2	Specialist
BERBAH	11	3	27.3	9.7	Specialist
KALASAN	18	3	16.7	9.7	Specialist
DANUREJAN I	16	1	6.3	3.2	Specialist
JETIS	20	1	5.0	3.2	Specialist

Table 13. The distribution of drop-outs by <i>Puskesmas</i> (N=31)	Table 13. The	distribution	of drop-outs by	v Puskesmas (N=31)
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The table below details the diagnoses which drop-outs received at baseline. This distribution is not markedly different from those who completed the trial. Those who dropped out were found not to have

any significant distinguishing demographic characteristics when compared to the rest of the group. There was no significant correlation between dropping out and any demographic variables.

	Frequency	Percent
Mild or Moderate Depressive Episode	6	19.4
Panic Disorder	2	6.5
Social Phobia	1	3.2
Generalised Anxiety Disorder	5	16.1
Mixed Anxiety And Depression	10	32.3
Other Disorder	7	22.6

Table 14. CIS-R Diagnosis Received by drop-out participants at Baseline (N=31)

There was a significant small correlation between dropping out and disability at baseline as measured by WHODAS 2.0 (Spearman's Rho = 0.21, p<0.001) and between dropping out and quality of life utility score as measured by the EQ5D (Spearman's Rho = -0.19, p<0.001). The difference in mean disability score among drop-outs, 35.63 (SD= 17.10) and trial completer, 23.62 (SD=16.32) was statistically significant, t (323) = -3.879, p<0.001. Those who dropped-out scored significantly higher in disability ratings at baseline compared to participants who completed the trial. The difference in quality of life (Malaysian) utility score among drop-outs, 0.70 (SD= 0.13) and trial completer, 0.79 (SD=0.13) was statistically significant, t (323) = 3.366, p<0.05. Those who dropped out had a significantly lower quality of life utility scores at baseline compared to participants who completed the trial.

4.5 Trial Outcomes

4.5.1 Primary Outcome (HoNOS)

Both groups experienced a similar improvement in the health and social functioning (HoNOS total score) at the 6-month follow-up: the regression coefficient of Specialist vs Enhanced Usual Care was - 0.55 (95%CI -1.69 to 0.58) with p=0.341 (Table 15). The bootstrap procedure gave 95%CI -1.46 to 0.35 with p=0.232. The re-analysis by using one-sided 97.5%CI showed that for Beta≤0 p=0.829. Multiple imputation analysis (31 observations imputed at follow-up) confirmed the result: the regression coefficient of Specialist vs WHO mhGAP was -0.55 (95%CI -1.67 to 0.56) with p=0.333.

Table 15. Means (SDs) and mixed-effects random regression coefficients of Specialist vs WHO mhGAP (95% CI) for primary (HoNOS) and secondary outcomes (EQ-5D and WHODAS 2.0) of patients assessed at baseline and 6-month follow-up (WHO mhGAP arm n=152, Specialist arm n=138)

PRIMARY OUTCOME	WHO mhGAP arm	Specialist arm	Regression coefficient [#] of Specialist vs WHO	p-value
		1	mhGAP (95% CI)	1

	BL (n=173)	FU (n=152)	BL (n=148)	FU (n=138)		
HoNOS TOTAL	4.96 (4.76)	3.46 (4.40)	6.47 (5.70)	3.43 (4.61)	-0.55 (-1.69 to 0.58)§	0.341§
SECONDARY OUTCOMES	WHO mł	nGAP arm	Specia	list arm	Regression coefficient [#] of Specialist vs WHO mhGAP (95% CI)	p-value
	BL (n=173)	FU (n=152)	BL (n=148)	FU (n=138)		
EQ-5D Utility Score	0.77 (0.14)	0.83 (0.11)	0.80 (0.13)	0.83 (0.11)	-0.01 (-0.02 to 0.01)	0.296
WHODAS 2.0 Total	25.82 (17.53)	(1 missing) 12.16 (14.04)	23.30 (15.85)	12.53 (13.98)	0.29 (-4.38 to 4.96)	0.903

[#] Random effects linear regression models with *Puskesmas* as a random effect and the corresponding baseline score and the treatment assignment as fixed effects

Multiple Imputation with 20 replications:

HoNOS (31 imputed observations at follow-up) Beta=-0.55, 95%CI (-1.67 to 0.56), p=0.333

EQ-5D (30 imputed observations at follow-up) Beta=-0.01, 95%CI (-0.02 to 0.01), p=0.187

WHODAS (31 imputed observations at follow-up) Beta=-0.02, 95%CI (-4.33 to 4.30), p=0.994

4.5.2 Secondary Outcomes

4.5.2.1 EQ-5D-3L

A similar improvement was estimated in both groups for the quality of life (EQ-5D Utility Scored using the Malaysian Algorithm: the regression coefficient of Specialist vs WHO mhGAP was -0.01 (95%CI -0.02 to 0.01) with p=0.296 (Table 15). The bootstrap procedure gave 95%CI -0.02 to 0.01 with p=0.312. The re-analysis by using one-sided 97.5%CI showed that for Beta \leq 0 p=0.852. Multiple imputation analysis (30 observations imputed at follow-up) confirmed the result: the regression coefficient of Specialist vs WHO mhGAP was -0.01 (95%CI -0.02 to 0.01) with p=0.187.

Table 16 indicates the numbers and proportions of trial participants reporting levels within each of the dimensions. A comparison of the proportions at baseline and follow-up, as well as an assessment of the change in the proportion of participants reporting problems, indicate a general improvement in health-related quality of life.

Table 16. Numbers and proportions of participants reporting levels within EQ-5D-3L dimensions
at Baseline and Follow-up

EQ-5D Level	Mob	oility	Self-	Care	Usual A	ctivities	Pain/Dis	scomfort	Anxiety/I	Depression
EQ-3D Level	BL	FU								
1	259 (78.7%)	262 (89.1%)	309 (95.1%)	284 (96.6%)	229 (70.5%)	252 (85.7%)	107 (32.9%)	196 (66.7%)	104 (32.0%)	169 (57.5%)
2	64	32	15	10	88	21	192	95	179	117

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	(19.7%)	(10.9%)	(4.6%)	(3.4%)	(27.1%)	(13.9%)	(59.1%)	(32.3%)	(55.1%)	(39.8%)
3	2 (0.6%)		1 (0.3%)		8 (2.5%)	1 (0.3%)	26 (8.0%)	3 (1.0%)	42 (12.9%)	8 (2.7%)
Total	325 (100%)	294 (100%)	325 (100%)	294 (100%)	325 (100%)	294 (100%)	325 (100%)	294 (100%)	325 (100%)	294 (100%)
Number Reporting Problems	68 (20.3%)	32 (9.8%)	16 (4.9%)	10 (3.1%)	96 (29.6%)	22 (14.2%)	218 (67.1%)	98 (33.3%)	221 (68.0%)	125 (42.5%)
% Change in Number	-10	.5%	-1.3	8%	-15	.2%	-33	.8%	-25	.5%
Rank in Terms Of % Changes	2	4	4	5		3	1	1	2	2

4.5.2.2 WHODAS 2.0

A similar amelioration was estimated in both groups for disability (WHODAS 2.0 total score) at followup: the regression coefficient of Specialist vs WHO mhGAP was 0.29 (95%CI -4.38 to 4.96) with p=0.903 (Table 15). The bootstrap procedure gave 95%CI -2.52 to 3.10 with p=0.840. The re-analysis by using one-sided 97.5%CI showed that for Beta>0, p=0.548. Multiple imputation analysis (31 observations imputed at follow-up) confirmed the result: the regression coefficient of Specialist vs WHO mhGAP was -0.02 (95%CI -4.33 to 4.30) with p=0.994.

	Baseline	Follow-up	Test and Significance of Difference
Domain 1: Cognition			
Overall	25.99 (18.49)	12.96 (16.57)	t=11.10, df=293, p=0.000
WHO mhGAP	25.39 (19.06)	11.73 (16.56)	t=7.91, df=152, p=0.000
Specialist	26.63 (17.90)	14.29 (16.54)	t=7.83, df=140, p=0.000
Domain 2: Mobility			
Overall	21.81 (21.22)	11.29 (16.88)	t=9.63 df=293, p=0.000
WHO mhGAP	24.06 (21.30)	11.44 (17.28)	t=7.92, df=152, p=0.000
Specialist	19.37 (20.93)	11.13 (16.50)	t=5.62, df=140, p=0.000
Domain 3: Self-care			
Overall	12.62 (18.59)	5.78 (12.88)	t=6.68, df=293, p=0.000
WHO mhGAP	13.99 (20.04)	11.44 (17.28)	t=5.35, df=152, p=0.000
Specialist	11.13 (16.82)	5.74 (12.49)	t=4.03, df=140, p=0.000
Domain 4: Getting Along			
Overall	18.65 (21.17)	9.67 (16.68)	t=7.68, df=293, p=0.000
WHO mhGAP	18.08 (21.65)	9.26 (16.38)	t=5.07, df=152, p=0.000
Specialist	19.27 (20.71)	10.11 (17.04)	t=5.90, df=140, p=0.000
Domain 5: Activities			
Overall	26.70 (24.44)	16.05 (20.34)	t=7.17, df=293, p=0.000
WHO mhGAP	27.78 (24.77)	16.54 (19.84)	t=5.08, df=152, p=0.000
Specialist	25.53 (24.12)	15.53 (20.92)	t=5.10, df=140, p=0.000
Domain 5b: Work			
Overall (n=173)	26.70 (24.45)	13.87 (17.64)	t=5.58, df=172, p=0.000
WHO mhGAP (n=84)	24.23 (20.92)	12.75 (17.46)	t=4.44, df=83, p=0.000
Specialist (n=89)	23.29 (22.75)	14.93 (17.85)	t=3.43, df=88, p=0.000
Domain 6: Participation			
Overall	28.16 (19.64)	14.57 (17.63)	t=11.07, df=293, p=0.000
WHO mhGAP	28.68 (19.34)	14.65 (17.11)	t=7.81, df=152, p=0.000
Specialist	27.60 (20.00)	14.48 (18.25)	t=7.87, df=140, p=0.000

Table 17. Means of WHODAS 2.0 Domain Scores at Baseline and 6-months Follow-up for participants who completed the trial (n=294, nWHO mhGAP=153, nSpecialist=141)

A significant reduction in all domains of disability as measured by the WHODAS 2.0 domain scores was found, for both treatment arms and overall (Table 17). Similarly, a significant reduction in disability at follow-up as measured by the overall WHODAS 2.0 score was found, for both treatment arms and overall (Table 15). The WHODAS 2.0 was found to have excellent Internal Consistency, Cronbach's alpha 0.90 at Baseline and 0.91 at Follow-up.

WHODAS 2.0 is additionally supplemented with three questions pertaining the number of days in the last 30 days where problems were present (Table 18).

	WHO mh	GAP arm	Special	list arm
	BL	FU	BL	FU
	(n=174)	(n=150)	(n=141)	(n=141)
Days Difficulty Present				
Mean (SD)	8.64 (10.20)	3.45 (4.99)	9.73 (10.28)	5.31 (6.22)
Median (IQR)	5 (9.0)	1 (7.0)	7 (13.0)	4 (10.0)
Minimum	0	0	0	0
Maximum	30	30	30	30
Days Unable to Carry Out Activities				
Mean (SD)	4.50 (8.23)	1.05 (2.33)	2.65 (5.66)	1.06 (3.36)
Median (IQR)	1 (5.5)	0 (1.0)	0 (3.0)	0 (0)
Minimum	0	0	0	0
Maximum	30	14	30	30
Days Cutting Back or Reducing Activities				
Mean (SD)	5.87 (8.41)	2.48 (4.36)	4.83 (7.53)	3.35 (5.86)
Median (IQR)	3 (7.0)	0 (4.0)	2 (7.0)	0 (5.0)
Minimum	0	0	0	0
Maximum	30	30	30	30

Table 18. Number of days affected by disability in the last 30 days as per WHODAS 2.0

4.6 Recovery and Remission

Among participants followed up from the WHO mhGAP arm (n=173) and the Specialist arm (n=151), a large proportion of participants were no longer meeting any diagnostic criteria according to CIS-R, and were considered in remission (n=152 and n=134 respectively).

The groups did not differ in many socio-demographic characteristics (Table 19), except that participants in the WHO mhGAP arm were older than those in the Specialist arm. Participants in the Specialist arm also tend to be more educated.

Looking at the response to treatment among participants who had one or more intervention sessions, there was greater improvement in health and social functioning among the Specialist arm participants (mean reduction in HoNOS score of 2.86, SD 5.40) compared to WHO mhGAP arm participants (mean reduction in HoNOS score of 1.11, SD 5.82). This difference is statistically significant (t=2.26, df=214, p=0.025).

In terms of disability, there was a greater overall improvement among the WHO mhGAP arm (mean reduction in WHODAS 2.0 score of 12.23, SD 18.46) compared to the Specialist arm (reduction of 9.84, SD 15.11). This difference is not statistically significant.

Table 19. Socio-demographics of patients in remission (n=286).

	WHO mhGAP arm (n=152)	Specialist arm (n=134)	Test and Significant Difference
Gender, n (%)			
Male	39 (26.4)	37 (29.3)	$\chi^2=0.14$, df=1, p=0.709
Female	113 (73.6)	97 (70.7)	
Age	(3 missing)	(1 missing)	
mean (SD)	44.3 (15.1)	39.0 (14.8)	t=2.98, df=282, p=0.003
median (IQR)	46.0 (23.0)	39.5 (26.0)	
Marital Status, n (%)			
Unmarried	30 (19.5)	42 (30.0)	χ ² =5.21, df=2, p=0.074
Married	108 (71.3)	80 (60.7)	
Separated, Divorced, Widowed	14 (9.2)	12 (9.3)	
Language, n (%)		(2 missing)	
Indonesian	16 (9.2)	25 (18.4)	χ ² =6.65, df=2, p=0.036
Javanese (fluent in Indonesian)	122 (81.6)	102 (78.2)	
Javanese (not fluent in Indonesian)	14 (9.2)	5 (3.4)	
Educational Level, n (%)			
Low (Elementary-Middle School)	76 (50.0)	42 (30.7)	χ^2 =10.23, df=1, p=0.001
High (High School, Diploma, Degree)	76 (50.0)	92 (69.3)	
Living Condition, n (%)	(1 missing)	(1 missing)	
Alone	18 (11.0)	22 (14.8)	χ ² =3.13, df=3, p=0.371
Partner	85 (53.8)	62 (46.3)	-
Relatives	17 (12.1)	15 (11.4)	
Parents	31 (23.1)	34 (27.5)	
Working Status, n (%)		(1 missing)	
Employed	71 (48.3)	75 (50.0)	χ ² =0.752, df=2, p=0.687
Unemployed	22 (13.8)	17 (11.3)	-
Housewife, Student, Retired, Volunteer	59 (37.9)	58 (38.7)	

4.7 Subgroup Analysis

The data show that 223 of 294 participants (75.9%) followed-up attended one or more sessions at a *Puskesmas* for the delivery of interventions. Those who did not take up the intervention on offer were found to be significantly younger than those who attended intervention (Table 20). For the subgroup analysis, participants who did not attend any intervention session during the trial period became part of the non-intervention group. Non-intervention group here differs from the traditional 'control' for cluster RCT defined as participants recruited in 'control' clusters. The non-intervention group includes participants recruited into the trial who met all the screening and diagnosis criteria for inclusion but did not receive any treatment for the duration of the trial. For the following analyses, participants were divided into three groups:

- 1. Non-intervention (n=71)
- 2. WHO mhGAP arm (n=126)
- 3. Specialist arm (n=97)

Table 20. Socio-demographics of participants for subgroup analysis (n=294).

Treatment Groups

Non-Intervention

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	WHO mhGAP arm (n=126)	Specialist arm (n=97)	Group (n=71)
Gender, n (%)	(')		
Male	33 (26.2%)	24 (24.7%)	25 (35.2%)
Female	93 (73.8%)	73 (75.3%)	46 (64.8%)
	. ,	$\chi^2=2.55, df=2, p=0.279$	10 (0 11070)
Age	(2 missing)	(1 missing)	(1 missing)
mean (sd)	44.6 (14.3)	40.16 (14.7)	37.0 (14.9)
median	46	41	35
		F=6.54, df=2, p=0.002	55
		r-0.34, di-2, p-0.002	
Marital Status, n (%) Unmarried	21 (16.7%)	21 (21.6%)	27 (38.0%)
Married	93 (73.8%)	66 (68.0%)	40 (56.3%)
Separated, Divorced, Widowed	12 (9.6%)	10 (10.3%)	40 (30.378) 4 (5.6%)
Separated, Divorced, widowed			4 (3.070)
	χ	² =12.21, df=4, p=0.016	
Language, n (%)			
Indonesian	11 (8.7%)	14 (14.9%)	16 (22.5%)
Javanese (fluent in Indonesian)	105 (83.3%)	77(81.9%)	49 (69.0%)
Javanese (not fluent in Indonesian)	10 (7.9%)	3 (3.2%)	6 (8.5%)
	2	ζ ² =9.88, df=4, p=0.043	
Educational Level, n (%)			
Low (Elementary-Middle School)	63 (50.0%)	31 (32.0%)	22 (31.0%)
High (High School, Diploma, Degree, Other)	60 (50.0%)	66 (68.0%)	49 (69.0%)
	χ	² =10.28, df=2, p=0.006	
Living Condition, n (%)			
Alone	12 (9.5%)	13 (13.4%)	14 (20.3%)
Partner	73 (57.9%)	48 (49.5%)	27 (39.1%)
Relatives	13 (10.3%)	12 (12.4%)	7 (10.1%)
Parents	28 (22.2%)	24 (24.7%)	21 (30.4%)
)	ζ ² =8.49, df=6, p=0.204	
Working Status, n (%)			
Employed	61 (48.4%)	51 (52.6%)	35 (49.3%)
Unemployed	13 (10.3%)	10 (10.3%)	10 (14.1%)
Housewife, Student, Retired, Volunteer	52 (41.3%)	36 (37.1%)	26 (36.6%)
		² =1.238, df=4, p=0.872	

The groups differ in several socio-demographic characteristics. The non-intervention group had significantly more participants who were younger, unmarried and primarily Indonesian speakers (Table 20). The WHO mhGAP group had more participants with lower educational qualification.

Resource use during the six months' period of the trial is reported by group in Table 21. Reasons for hospital inpatient service varied and mostly involved admission to the general ward. Hospital and *Puskesmas* outpatient service also varied, and no one type of service was predominant. There were no admissions to Accident and Emergency reported by any participant. Attendance at intervention sessions was on average once a month for both treatment groups.

Table 21. Resource use by group during the trial period.

	WHO mhGAP arm	Specialist arm	Non-intervention
	(n=126)	(n=97)	(n=71)
Inpatient (night)			
n (%) of users	10 (7.9)	13 (13.4)	1 (1.4)
mean (sd)	0.67 (2.50)	1.81 (5.31)	0.08 (0.71)
median	0	0	0
maximum	13	26	6
Outpatient (attendance)			
n (%) of users	41 (32.5)	29 (29.9)	2 (2.8)
mean (sd)	1.06 (1.69)	1.30 (2.28)	0.07 (0.43)
median	0	0	0
maximum	5	10	3
Intervention Session (attendance)			
n (%) of users	126 (100.0)	97 (100.0)	0 (0.0)
mean (sd)	5.44 (2.95)	5.81 (2.74)	
median	5	5	
maximum	9	9	

Across all groups, participants show significant collective improvements in their HoNOS and WHODAS 2.0 scores, as well as their health-related quality of life index scores (Table 22).

Table 22. Means of Outcome Variables at Baseline and 6-months for participants included in the
Economic Analyses (n=294)

	Baseline (SD)	Follow-up (SD)	Test and Significance of Difference
HoNOS Total Score			
Non-intervention (n=71)	5.30 (4.62)	2.86 (3.85)	t=3.98, df=70, p=0.000
WHO mhGAP (n=126)	4.55 (4.50)	3.45 (4.38)	t=2.11, df=122, p=0.037
Specialist (n=97)	6.75 (5.88)	3.89 (4.85)	t=5.11, df=92, p=0.000
WHODAS 2.0			
Non-intervention (n=71)	23.50 (14.81)	12.29 (14.28)	t=6.18, df=70, p=0.000
WHO mhGAP (n=126)	24.75 (16.89)	12.53 (13.99)	t=7.40, df=124, p=0.000
Specialist (n=97)	22.34 (16.13)	12.49 (13.63)	t=6.41, df=96, p=0.000
EQ-5D			
Non-intervention (n=71)	0.79 (0.13)	0.83 (0.11)	t=-5.41, df=70, p=0.000
WHO mhGAP (n=126)	0.78 (0.13)	0.83 (0.11)	t=-8.54, df=125, p=0.000
Specialist (n=97)	0.80 (0.13)	0.83 (0.11)	t=-4.89, df=96, p=0.000

While all groups reported significant differences between baseline and follow-up scores (Table 22), there are no significant differences between the three groups in any of the outcome variables at six months after baseline. The non-intervention group recovered as well as the treatment groups.

The table below shows participants' report of the number of days affected by disability in the last 30 days prior to baseline and follow-up assessments, as measured by the WHODAS 2.0.

Table 23. Number of days affected by disability in the last 30 days as per WHODAS 2.0

	BL	FU	BL	FU	BL	FU
	(n=126)	(n=126)	(n=97)	(n=97)	(n=71)	(n=71)
Days Difficulty Present						
Mean (SD)	8.85 (10.48)	3.72 (5.24)	9.34 (9.98)	5.46 (6.31)	9.48 (10.28)	3.92 (5.37)
Median (IQR)	4.5 (10)	1 (7.0)	7 (13.0)	4 (10.0)	7 (13.0)	1 (5.0)
Minimum	0	0	0	0	0	0
Maximum	30	30	30	30	30	20
Days Unable to Carry Out Activities						
Mean (SD)	4.28 (7.98)	1.21 (2.52)	2.68 (5.22)	1.12 (3.73)	3.71 (7.85)	0.69
Median (IQR)	1 (4.3)	0 (1.0)	0 (3.0)	0 (0.0)	0 (2.0)	0 (0.0)
Minimum	0	0	0	0	0	0
Maximum	30	14	30	30	30	10
Days Cutting Back or Reducing Activities						
Mean (SD)	5.84 (8.75)	2.60 (4.55)	4.94 (7.48)	3.74 (6.38)	5.13 (7.35)	2.27 (4.06)
Median (IQR)	3 (7.0)	0 (4.0)	2 (7.0)	0 (5.0)	2 (7.0)	0 (4.0)
Minimum	0	0	0	0	0	0
Maximum	30	30	30	30	30	19

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Most of the 294 participants (73.1%, 215) followed-up reported the same or a reduction of the number of days affected by difficulty in the 30 days prior to follow-up compared to baseline. This included 50 of the Non-intervention Group (70.4%), 102 of the WHO mhGAP arm (81.0%), and 63 of the Specialist arm (64.9%). The rest reported an increase in the number of days affected by difficulty.

Most of the 294 participants (88.8%, 261) followed-up reported the same or a reduction in the number of days unable to carry out activities in the 30 days prior to follow-up compared to baseline. This included 63 of the Non-intervention Group (88.7%), 108 of the WHO mhGAP arm (85.7%), and 90 of the Specialist arm (92.8%). The rest reported an increase in the number of days they were unable to carry out activities.

Most of the 294 participants (75.8%, 223) followed-up reported the same or a reduction of the number of days they had to reduce activities in the 30 days prior to follow-up compared to baseline. This included 57 of the Non-intervention Group (80.2%), 97 of the WHO mhGAP arm (77.0%), and 69 of the Specialist arm (71.1%). The rest reported an increase in the number of days they had to reduce activities.

4.8 Economic Analysis

4.8.1 Perspective

As described in the trial protocol (Chapter 3), the economic evaluation took a health systems perspective and included the use of all health resources including *Puskesmas* follow-up services, overnight hospitalisation, and visits to hospital emergency. Our participants did not report any visits to hospital emergency during the trial period. Due to the relatively easy access to specialist physicians, Indonesians seldom visit hospital emergency except for acute and severe situations, like traffic accidents.

4.8.2 Participants

The figure below describes the flow of participants from recruitment at baseline to follow-up and subsequent economic analyses.

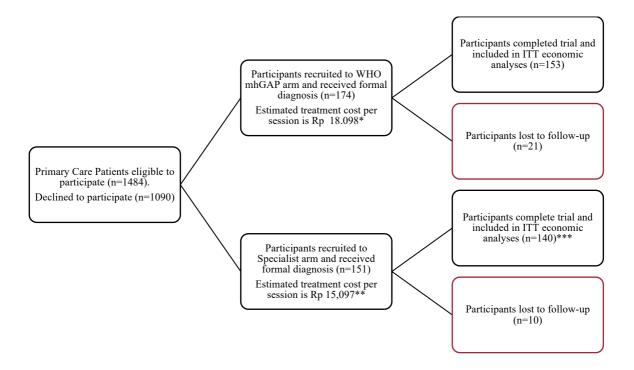


Figure 11. Modified CONSORT diagram for economic analyses

* data from Fidiyawati (2013) adjusted to 2017 rate

** crude estimate based on the mandated monthly income of clinical psychologists divided by aggregate number of appointments

*** HoNOS data at follow-up was only available for 140 Specialist Arm participants despite 141 participants completing the trial

4.8.3 Resource Use

For all trial participants, service use was recorded using a modified version of the Client Service Receipt Inventory. At the follow-up, participants were asked to recall their utility of health resources during the trial period (6 months). Table 24 below shows the use of inpatient services (number of overnight stays), outpatient medical care (number of appointments), as well as mental health intervention sessions at a *Puskesmas* (number of appointments). A greater proportion of participants returned for intervention sessions at the WHO mhGAP arm (82.4%) compared to the Specialist Arm (68.8%). The trial was unable to capture the cost of prescribed medication during the trial, as records on prescriptions filled within each *Puskesmas* were inconsistent between *Puskesmas*. All *Puskesmas* allowed patients to fill prescriptions from private doctors at the *Puskesmas*. Some *Puskesmas* record this within patients' medical records, while others do not. As such, it would be difficult to calculate an accurate aggregate cost of mental health care alone.

	WHO mhGAP arm	Specialist arm
	(n=153)	(n=141)
Inpatient (number of nights)		
n (%) of users	11 (7.2)	13 (9.2)
mean (sd)	0.59 (2.32)	1.25 (4.48)
maximum	13	26
Outpatient (number of appointments)		
n (%) of users	43 (28.1)	29 (20.6)
mean (sd)	0.90 (1.59)	0.89 (1.98)
maximum	5	10
Intervention Session (number of appointments)		
n (%) of users	126 (82.4)	97 (68.8)
mean (sd)	4.48 (3.39)	4.00 (3.53)

Table 24. Average resource use by each Treatment Arm during the trial period (6 months).

4.8.4 Costs and Outcomes

maximum

Based on the 2014 report (most recent publicly available), the ratio of *Puskesmas* doctor to catchment area residents in Yogyakarta is 1:5999 (Kisworini, 2015). The same report indicates that in 2014, each *Puskesmas* doctor had on average 10220 consultations. District Governments own all *Puskesmas* buildings, and there is no rental to be paid on the land and building for each *Puskesmas*. Residents of each *Puskesmas*' catchment area receive free healthcare from a *Puskesmas*.

10

10

The table below details average costs over six months and outcomes for all participants who completed the trial. Average HoNOS scores at baseline was significantly higher among the Specialist arm participants (mean of 6.25, SD=5.57) compared to WHO mhGAP arm (mean of 4.76, SD=4.72), adjusted mean difference of -1.49. There was little difference in utility scores between trial arms and across follow-up, which resulted in small differences in QALYs between trial arms (Table 25).

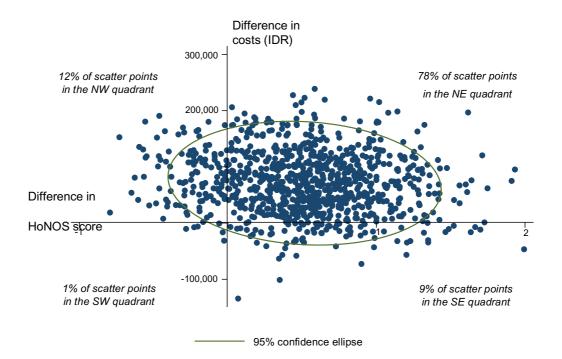
	WHO mhGAP arm (I) N=153 Mean (SD)	Specialist arm (C) N=141 Mean (SD)	Unadjusted mean difference (I-C)	Adjusted mean difference (I-C)		
				estimate	95% CI	p-value
Costs						
Intervention	17481	30468	-12987			
MH Treatment	81145 (61377)	60388 (53253)	20807	20397	7163 to 33632	0.004
Total Cost	98626 (61377)	90856 (53253)	7770	7410	-5823 to 20645	0.2
HoNOS Total						
Baseline	4.76 (4.72)	6.25 (5.57)	-1.49	-1.41	-0.26 to 2.55	0.04
6-months	3.48 (4.39)	3.44 (4.59)	0.04	-0.1	-1.3 to 1.1	0.9
Utility scores						
Baseline	0.78 (0.14)	0.80 (0.13)				
6-months	0.83 (0.11)	0.83 (0.11)				
QALYs						
6-months	0.4015 (0.060)	0.4082 (0.059)	-0.0067	-0.0067	-0.02 to 0.007	0.6

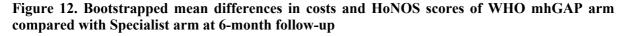
Table 25. Mean Outcomes per Participant over the trial period (6 months)

4.8.5 Cost-Effectiveness Analysis using HoNOS

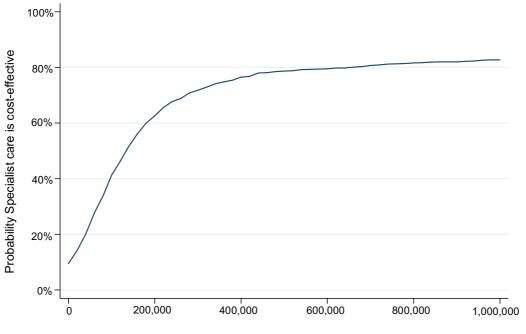
For the primary cost-effectiveness analysis using HoNOS scores, the lower costs and better outcomes in the Specialist framework generate an ICER of Rp 4,843 per unit improvement in HoNOS score, which suggest that the Specialist framework that the Specialist framework may be better able to improve health and social functioning for the same cost as the WHO mhGAP framework

Figure 12 shows the scatterplot of bootstrapped mean differences in costs and HoNOS outcome. The majority of the scatter points indicate that the Specialist framework is more effective than WHO mhGAP framework (to the right of the y-axis) and lie in the northeast quadrant (78%) where the Specialist framework is more effective but more costly, and the southeast quadrant (9%) where the Specialist framework is more effective and less costly. The remaining scatter points show poorer outcomes for the Specialist framework compared to the WHO mhGAP framework and fall in the northwest (12%; less effective, more costly) and southwest (1%; less effective, less costly) quadrants.





IDR: Indonesian Rupiah NW: North-West NE: North-East SW: South-West SE: South-East The CEAC for the primary analysis suggests that the probability of the Specialist framework being costeffective compared to the WHO mhGAP framework ranges from just under 10% at a zero willingness to pay for a unit of improvement in HoNOS score to over 80% at a Rp 1,000,000 willingness to pay threshold (Figure 13). The point at which the Specialist care has a higher probability of being costeffective compared to the WHO mhGAP arm (i.e. probability >50%) is at a willingness to pay level of Rp 150,000 per unit improvement in HoNOS score.



Willingness to pay (IDR) per unit improvement in HoNOS score

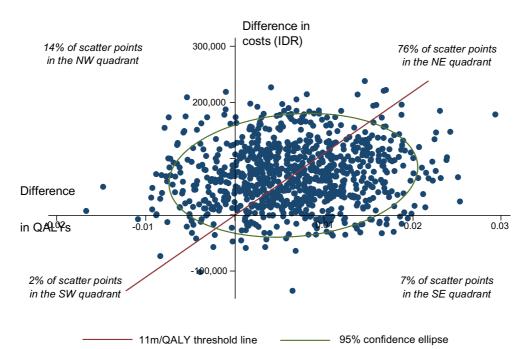
Figure 13. Cost-effectiveness acceptability curve showing the probability that Specialist framework is cost-effective compared to WHO mhGAP for different values of willingness to pay thresholds using the HoNOS score at 6-month follow-up

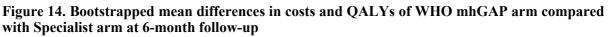
IDR: Indonesian Rupiah

4.8.6 Cost-Utility Analysis

For the secondary cost-utility analysis, the lower costs and marginally better outcomes in the Specialist framework generate an ICER of - Rp 11,105,970 per QALY which suggest that the Specialist framework dominates the intervention at the 6-month follow-up point.

Figure 14 shows the scatterplot of bootstrapped mean differences in costs and QALYs. The majority of the scatter points indicate that Specialist framework is more effective than WHO mhGAP framework (to the right of the y-axis) and lie in the northeast quadrant (78%) where the Specialist framework is more effective but more costly, and the southeast quadrant (7%) where the Specialist framework is more effective and less costly. The remaining scatter points show poorer outcomes for Specialist framework compared to WHO mhGAP framework and fall in the northwest (14%; less effective, more costly) and southwest (2%; less effective, less costly) quadrants.





IDR: Indonesian Rupiah

NW: North-West

NE: North-East

SW: South-West

SE: South-East

The CEAC for the cost-utility analysis suggests that the probability of the Specialist framework being cost-effective compared to WHO mhGAP framework is at 50% at the Indonesian willingness to pay for medical interventions of Rp 11,000,000 per QALY (Figure 15).

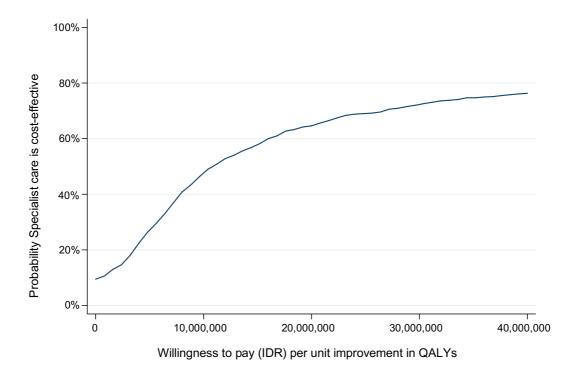


Figure 15. Cost-effectiveness acceptability curve showing the probability that Specialist framework is cost-effective compared to WHO mhGAP for different values of willingness to pay thresholds using QALYs at 6-month follow-up

IDR: Indonesian Rupiah

5 DISCUSSION AND CONCLUSIONS

In this real-life study comparing different delivery options for primary mental health care in a lower middle-income country (Indonesia), several expected and unexpected outcomes were discovered.

5.1 Principal Outcomes

The GHQ-12 was established as a 'fairly accurate' screening tool for psychiatric morbidity among primary care patients. Using the GHQ scoring method of 0-0-1-1, Chapter 2 concluded with the following recommended threshold scores. For use in the clinical setting, a threshold of 1/2 is recommended, where a total score of 2 or above signify a likelihood of psychiatric morbidity. In a research setting, a higher threshold of 2/3 is recommended, where a total score of 3 or above merit inclusion into a clinical sample.

The cluster randomised controlled trial described in Chapter 3 explored two core aims:

- 1. the *clinical effectiveness* of the adapted WHO mhGAP approach of primary mental health care versus a Specialist model (co-location of clinical psychologists in primary care) at six months
- 2. the *cost-effectiveness* of the adapted WHO mhGAP approach of primary mental health care versus a Specialist model (co-location of clinical psychologists in primary care) at six months.

The WHO mhGAP arm was proven to be statistically not inferior to the Specialist arm in reducing symptoms of social and physical impairment, reducing disability, and improving health-related quality of life at six months. In both treatment arms, large proportions of participants went into remission. The WHO mhGAP arm had a higher percentage of patients returning for intervention than the Specialist arm. Patients reporting a diagnosis of hypertension at baseline screening, were found to have significantly less improvements compared to those who did not.

The primary cost-effectiveness analysis, comparing outcomes concerning HoNOS scores suggested that the Specialist arm may be cost-effective compared to WHO mhGAP arm at 6-months, despite the employment of clinical psychologists costing the health system additional spending. Secondary cost-effectiveness analysis using QALYs indicate the 50% probability of the Specialist arm being more cost-effective than the adapted WHO mhGAP at the Indonesian willingness to pay for medical interventions of Rp 11,000,000 per QALY.

Data gathered could be used to explore the acceptability of the adapted WHO mhGAP approach versus a Specialist co-location model in primary care.

5.2 Strengths and Weaknesses

The trial was the first study of its kind in Indonesia, where despite the Specialist framework having existed for over 10 years, there was no empirical study which examined its clinical effectiveness and cost-effectiveness. The systematic introduction of the adapted WHO mhGAP framework into the

country's primary care system allowed a pragmatic cluster randomised controlled trial to examine the impact of both frameworks in the Indonesian context. It also provided the rare opportunity to conduct a statistically robust trial in a 'real-life' setting. The trial recruited to target and retention in the six months was high (90.4%).

As this is a pragmatic trial, efforts were made to reflect the 'real life' conditions as far as possible. Reflecting the lack of Ministry of Health monitoring of the use of the WHO mhGAP Intervention Guide among those who received the training, this trial chose to not enforce the adherence of the WHO mhGAP treatment arm to the Intervention Guide. As such, this trial did not control what the clinicians used from their adapted WHO mhGAP training, which has been regarded by the Ministry of Health as an add-on to *Puskesmas* doctors' competency standards. The ITT approach was used in the design, conduct, and analysis of the trial, reducing the potential for an overly optimistic estimate of the efficacy of both frameworks.

While it is beneficial to reflect on-the-ground lack of monitoring as is, it could also be considered a weakness, as there is no way of ensuring if the adapted WHO mhGAP training received by *Puskesmas* doctors had any contribution to the treatment outcomes of their patients. Future studies should attempt to incorporate this assessment. A third treatment arm comprising Puskesmas doctors who did not attend the adapted WHO mhGAP training could have been considered as a third arm in the trial.

While a clinical trial typically requires enormous budgets and a large manpower base, following the timeline of the Indonesian Ministry of Health and collaborating with Health Authorities at district and provincial levels, and matched-funded collaborators enabled significant reductions of resources required. The adapted WHO mhGAP "standardised" training was conducted by a dedicated team from the Ministry of Health, which was an advantage in terms of external validity, in that training was not restricted to only those who participated in the trial, highlighting the pragmatic nature of the study.

Conducting a pragmatic trial without the backing of a large research grant from one principal funder was challenging, and it is no wonder that few people have attempted this. This trial proved that it can be feasible and that the payoff is enormous. However, the length of the recruitment period and the overall size of the trial was a function of funding constraints. Moreover, delays with the start of the trial and the time restriction of a PhD degree allowed only a six-month follow-up and nothing further.

The trial methodology established a systematic procedure for the identification of primary care patients with psychiatric morbidity. The trial also achieved its primary objectives of evaluating the clinical and cost-effectiveness of the adapted WHO mhGAP and Specialist frameworks.

This trial reflects what happens outside laboratory conditions, when general practitioners employed in state-run primary care clinics were provided an additional framework of care to treat their patients, compared to clinical psychologists treating patients as per routine. The trial could not impose any

control of what kind of intervention each clinician provided participants with but was more concerned instead with the impact of clinicians' academic and add-on training backgrounds on job performance, i.e. patient outcomes.

While the pragmatic nature is an advantage, the size of recruitment and delivery of intervention do have disadvantages. As with many mental health trials, there will always be concerns about the potential bias in the response of those patients who agreed to participate in research. The nature of the recruitment process which we agreed on with the health services did mean it was impossible to estimate the demographic profiles of those who refused to participate.

The recruitment procedure, unfortunately, created a long waiting time in clinics for those who agreed to participate. As such, there were inevitably dropouts even before the recruitment interview took place.

A significant issue with the economic evaluation pertains to the reliance on patient recall and report of health services utilisation, which for many reasons may be under- or over-reported. Moreover, the lack of Indonesian utility indices for EQ-5D-3L resulted in a reliance on Thai and Malaysian indices. Both Malaysia and Thailand are Indonesia's geographical neighbours with similar cultural practices. However, the Thai and Malaysian indices were rather different, causing uncertainties about which indices should be adopted for this trial's analyses. Eventually, the Malaysian utility index was chosen over the Thai due to higher proximity in culture and religion to Indonesia.

The development of mapping algorithms enables researchers to translate information gained from preference-based measurements into health state utility weights for use in economic evaluations. Although NICE recommends the use of mapped health state utility estimates when directly collected data are not available, the validity of these mapping methods has not been fully addressed. It has been argued that current methods for mapping are not known to be conceptually robust (Round and Hawton, 2017) and carries a "significant risk that may be harmful to population health" (McCabe et al., 2013). It is therefore important to consider the results of the mapped cost-utility analysis with greater uncertainty, especially when making country-wide decisions.

The cost-utility analysis used a willingness-to-pay (WTP) threshold of Rp 11,000,000.00 for medical intervention in the country (Kristina et al., 2017), which was determined using a pay-for-service perspective, i.e. when patients must pay for interventions out of pocket. There is a lack of established Indonesian WTP threshold for medical interventions from the health systems perspective. What individuals are willing to pay out of pocket is likely to differ from a structural, top-down perspective of the country's universal health coverage system. As this study aims to assist the Indonesian Ministry of Health in the scale-up of the most appropriate primary mental health service framework, the lack of established WTP threshold from the health systems perspective is significant.

Findings support existing literature in that he primary outcome, HoNOS, was able to detect change in the community for those with common mental disorders (Rees et al., 2004) and those with higher HoNOS scores at the diagnosis (Parabiaghi et al., 2005), such as in the average mean scores of our Specialist arm participants at baseline.

The culture of rent-seeking and bribery (or even discrimination) embedded within the primary care system resulted in inconsistent buy-in among gatekeepers (Heads of *Puskesmas*). One Head of Puskesmas (Cluster B3), sought support (bribes) for his son's high school tuition fees, rejected screening for the first few days of recruitment, and placed the clinical psychologist on leave for the remaining duration of recruitment. As a result, cluster B3 was dropped out of the trial. Other researchers willing to offer bribes were able to bypass established regulations. While during this trial my research assistants and I were not allowed to view medical record files without supervision, let alone take them out of the *Puskesmas*, some researchers agreeing to bribe received special privileges. For example, in one WHO mhGAP cluster (*Puskesmas*), a different research project could 'borrow' medical record files and took them out of the premises of the *Puskesmas*. As a result, we were unable to follow-up with most participants from this cluster, as their medical record files went missing. The *Puskesmas* official did not have any information on who "borrowed" the files and therefore could not retrieve them.

5.3 Possible Mechanisms and Explanations of Findings

As hypothesised, the adapted WHO mhGAP framework was found to be not inferior to the Specialist model. This result should be viewed keeping in mind that most participants had mild to moderate severity of disorders. Relatively brief psychosocial therapy was perhaps sufficient, where a more elaborate intervention plan might be required for severe disorders. The Specialist arm started out with higher ratings of morbidity (more severe cases) but could reduce the severity ratings to levels similar to those of the WHO mhGAP arm.

The percentage of participants returning to intervention by Clinical Psychologists were markedly lower than the WHO mhGAP arm. It is possible that participants did not return for intervention due to stigma, or the belief that it does not work, or other reasons. In-depth qualitative research needs to shed light on this.

A sizeable minority of participants from the Specialist arm who screened positive for psychiatric morbidity declined the offer of a free intake interview and, if applicable, intervention. It was possible that they did not fully understand the work of psychologists. Two patients from a particular cluster, representing 5% of patients who declined the offer of an interview/intervention, explicitly requested for a free intake interview and intervention to be provided by a clinical psychologist from private practice instead, expressing concerns regarding the competence of *Puskesmas* psychologist.

The low return rate would not be a surprise to clinicians involved. Psychologists I spoke to during one of the trainings for the trial procedures mentioned that, in general, few patients returned for intervention. There is potentially a limited understanding among patients of psychologists that intervention takes a few sessions and must be completed. The low return rate for intervention could indicate the belief among patients that one session with a psychologist could already cure them of their symptoms. This could be due to psychologists not telling their patients explicitly their treatment plans, which would require several sessions. While the idea of a 'one-session fix' could be attributed to the lack of communication regarding treatment plans with patients, there are indications that psychologists seldom develop treatment plans. The big perceived knowledge gap between service providers and services users might also contribute to the lack of psychoeducation, or at least an explanation of the current prognosis and what could be done to improve the situation. On the other hand, there are indications that patients talk among themselves about the perceived effectiveness of an intervention, and where the experience was perceived to be negative, word will spread regarding the perceived incompetence of a clinician in the community.

Unlike their medical counterpart, clinical psychology training in Indonesia might lack consistency specifically in the training of clinical interventions. Based on my observation in January 2016, the training of clinical psychologists in Indonesia is such that theories of aetiology and presentation of symptoms were prioritised over the development of practical skills through observations and clinical placements, as well as the practice of standardised therapeutic approaches and formulating a treatment plan. Master of Clinical Psychology theses at the largest state university in Yogyakarta are generally a thorough case study of a patient, rather than an evaluation of a therapeutic intervention characteristic of a Western programme, built upon an apprenticeship with intensive supervisions.

There might be a general lack of knowledge among clinicians that home visit, while time-consuming, attract additional funding for the *Puskesmas* (i.e. paid for by the country's universal health coverage). The inertia caused by busy clinic hours might have resulted in a lack of follow-up even for patients who required intervention. Unlike medical practitioners who had to pass a rotation in A&E, are familiar with ward rounds and follow-up care, and are facing oversubscribed clinic hours every day, psychologists did not work under time pressure. Participants in the Specialist treatment arm had a much higher rating of symptom intensity as measured by the CIS-R, but at the end of the trial period had this rating lowered to levels similar to those in the WHO mhGAP treatment arm.

The Javanese ethos "*alon alon asal kelakon*" – translated as "slowly, slowly, so long as it gets done one day" – seems to remain pervasive despite the demands of modernisation. As this may influence the rate of participants' return to *Puskesmas* for intervention, a trial period of only six months is in hindsight too short for Yogyakarta. A more extended trial period is likely to increase the return rate, although the number of participants lost to follow-up could increase.

Participants who did not attend any intervention still remitted and had positive clinical outcomes. They recovered just as well as participants who attended intervention sessions in either treatment arms. There are several hypotheses regarding this phenomenon:

- 1. that the clinical instruments used in this trial lack criterion validity;
- 2. that positive outcomes were due to other variables, and not either framework of care;
- the episodic manifestation of mood disorders is such that symptoms while debilitating when they occur – may come and go and the absence of effective intervention may result in a more severe relapse;
- 4. the very nature of psychiatric morbidity cannot yet be assessed through physiological tests, and reliance on patients' self-reporting carry its own intrinsic biases;
- 5. regression fallacy, where remission or the perceived clinical effectiveness of both frameworks were merely a regression to the mean.

When instruments used to assess outcomes lack criterion validity, any effects of the frameworks in question may not be reflected in these outcomes. While possible, it is unlikely that several standardised instruments on health and social impairment, disability, and health-related quality of life all lack criterion validity. Other hypotheses are therefore more likely.

An awareness of psychiatric morbidity established during recruitment might be sufficient to encourage positive changes in lifestyle or strengthening of social support among participants. These variables outside the remit of the trial may contribute to overall good clinical outcomes. In a tightly-knit Javanese community, social support was adequately available. The living arrangement where three generations cohabit under one roof is still prevalent in Java. It is common for parents to work while the children are looked after by grandparents at home. Homes in Yogyakarta are also likely to have been passed down through generations, and as such neighbours are very closely-knit.

Overall positive clinical outcomes among participants could also be attributed to the episodic manifestation of mood disorders, where "improvements" were potentially captured during the progression of the illness, not recovery, and without any guarantee that relapse would not occur. While depression is a highly recurrent condition, the relapse is usually due to several risk factors, including genetics, gender, and psychosocial functioning, including prior history (Burcusa and Iacono, 2007). The stress generation hypothesis proposed that recurrent depressives generate stressful conditions for themselves, and are prone to relapse (Harkness et al., 1999). For others, coping with the single precipitating event would enable them to recover. The lack of long-term follow-up made it impossible to test this hypothesis.

Next, the reliance on participants' self-reporting of their symptoms carries its own intrinsic biases. A cultural bias could be true especially in the Javanese community, where suffering is considered part and parcel of life – humans having sinned against God - and that one must not complain about hardships –

the cultural concept of acceptance or "*nrimo*" (Subandi et al., 2014). The shame of being weak could prevent participants from disclosing any undesirable physical and mental states, especially as followup interviews were conducted at home. Despite ensuring that each follow-up interview took place in private, the presence of family members within the home could present undue stress causing "faking-good".

Given that patients who did not attend any intervention sessions were found to improve, it is possible that initial elevated measurements of symptom frequency and severity could be due to natural random variation in the presence of these symptoms at any given time. Given that the baseline interview took place while patients were at a *Puskesmas* for a physical ailment, it is also possible that elevated symptoms like the "white coat effect" happened. Patients may have felt inclined to inflate their experience of symptoms to legitimise their presence at the *Puskesmas*. Improvements across both treatment arms, as well as those who did not attend any intervention, could be attributed to coincidental improvements rather than a treatment effect.

Additionally, there might be spillover effects in the health-related quality of life of residents of specific geographical areas. Considering participants were recruited from specific *Puskesmas*, it was possible that they shared experiences and strategies for improvement with each other, thereby collectively reducing symptoms and improving wellbeing. Spillover effects might explain the general improvements experienced by all participants, including those who did not attend intervention sessions.

Links between physical and mental health have long been established (Clarke and Currie, 2009). Participants with comorbid hypertension at baseline were found to have significantly less improvements than those who did not. A critical review of the literature found two types of link between depression and hypertension, the first being related to amine depletion induced by medication, and the second pertaining to the consequences of hypertensive illness (Huapaya and Ananth, 1980).

A significant proportion of participants were categorised as having mixed anxiety and depression, as per their CSI-R score (25% in the WHO mhGAP arm, and 37% in the Specialist arm) at baseline. This finding is in line with a study conducted among general practice patients in Australia, which found 25% point prevalence rate of comorbid depression and anxiety, and where general practitioners are deemed well placed to identify and manage these illnesses (Tiller, 2013). The same study found that there is often a treatment gap, where around 40% of people with current disorders did not seek treatment, and from those who did, only 45% had access to effective treatment. In the Indonesian context, where specialist care is often inaccessible, the primary care is expected to deal with the comorbidity. Tiller (2013) also noted that while there are effective treatments for either depression or anxiety, there is a paucity of data about the treatment for comorbid anxiety and depression, and thus the two are still treated separately. The two disorders share many common symptoms (including somatic complaints) and similar risk factors which are likely to include the interactions between environmental and genetic

factors, and cognitive behavioural therapy has been proposed as an effective treatment (Pollack, 2005). There is abundant evidence for abnormalities of the norepinephrine and serotonin neurotransmitter systems in both depression and anxiety disorders (Ressler and Nemeroff, 2000) and more recently the role of gamma aminobutyric acid (GABA) in both disorders (Kalueff and Nutt, 2007). The significant of proportion of participants with mixed anxiety and depression is therefore not a surprise.

Regarding cost-effectiveness, the Specialist Arm had on average lower costs for intervention because of two possible reasons. Firstly, the average hourly cost of Clinical Psychologists in *Puskesmas* is lower than that of General Practitioners. Secondly, there are fewer follow-up appointments made with a Puskesmas psychologist (97 recorded sessions) compared to Puskesmas doctors (126 recorded sessions). Despite the higher initial cost, i.e. to receive free psychology consultations, a patient needs first to be referred by a General Practitioner, overall aggregate of treatment cost (initial interview and intervention combined) was slightly lower than the WHO mhGAP arm. Coupled with more substantial improvements in health outcomes, the Specialist Arm was the more cost-effective option. For the health system, however, the employment of Clinical Psychologists require additional spend on staff.

While the Specialist arm *Puskesmas* had more patients who screened positive for psychiatric morbidity, many more patients declined participation in the trial, compared to patients in the WHO mhGAP arm. Primary care patients' general preference for GP over Clinical Psychologists might indicate that there is possibly still fear of the unknown or even stigma of mental illness. Coupled with the fear of high intervention costs once the research project ends, patients might be reluctant to explore their mental health in a clinical setting.

5.4 Comparison with Existing Literature

While the first WHO mhGAP Intervention Guide was used by over 80 countries and translated into more than 20 languages, few research studies had directly addressed the utility of the mhGAP framework in LMICs, highlighting the pressing need for evidence (Dua et al., 2016). A recent systematic review of the WHO mhGAP evidence from LMICs found 13 studies describing the training of health workers using the WHO mhGAP Intervention Guide (Appendix J) but only nine studies describing the clinical implementation of the WHO mhGAP framework in LMICs (Keynejad et al., 2018):

- 1. In **Ethiopia**, a survey of experiences, strengths, and challenges of integrating mental health in primary health centres was conducted (Ayano et al., 2017).
- 2. Charlotte Hanlon and team (2016) proposed a randomised, controlled, non-inferiority trial based on task-sharing model also in **Ethiopia**, where health centre nurses and health officers were trained to deliver mental health care for people with severe mental disorders, based on the WHO mhGAP framework (Hanlon et al., 2016).

- 3. In **Haiti**, a retrospective chart review of outpatient assessments using the WHO mhGAP framework was conducted (Grelotti et al., 2015).
- 4. A mixed methods study of acceptability and patient satisfaction of mental health care plan designed by staff trained using the WHO mhGAP framework was conducted in **Nepal** but did not examine clinical outcomes (Jordans et al., 2016).
- 5. A study in **Afghanistan** examined the functionality and acceptability of a WHO mhGAP mobile application used by primary health centre clinicians but did not consider patient outcomes (Khoja et al., 2016).
- 6. Several studies in Kenya, including an evaluation of a WHO mhGAP mobile application for depression screening and a longitudinal non-randomised interventional study of adult patients seeking care for depression from rural public healthcare workers or traditional health practitioners trained in WHO mhGAP framework were conducted (Musyimi et al., 2017a, Musyimi et al., 2018, Musyimi et al., 2017b). Over three months, patients who sought care from traditional health workers were found to have significant reductions in depression symptoms as measured by the Beck Depression Inventory.
- 7. In **Zambia**, an RCT of WHO mhGAP framework intervention for alcohol problems with an 8week follow-up was conducted at a hospital in Lusaka (Sheikh et al., 2017). The intervention group was found to have a significantly longer abstinence period.

Studies by Musyimin et al (2017a) in Kenya and Sheikh et al (2017) in Zambia were the only two existing literature reporting patient outcomes for interventions conducted with the WHO mhGAP framework. Studies proposed by Hanlon et al (2016) to take place in Ethiopia and conducted by Sheikh et al (2017) in Zambia were the only two existing literature reporting a robust experimental design. The trial reported in this thesis is hitherto the only completed evaluation of an adapted WHO mhGAP framework looking at patient outcomes with robust experimental design taking place in 'real life' primary care setting.

On the other hand, literature evaluating the effectiveness of collaborative colocation of psychologists in primary care is even more limited, despite the abundance of articles extolling the virtues of a collaborative care model. Looking at the colocation of psychologists in primary care, a report shows between 14% (South Dakota) to 50% (Rhode Island) general practitioners sharing practice with a psychologist in American states (Miller et al., 2014). The same report stated a positive correlation between the state supply of psychologists and the percentage of colocation (Pearson's r = 0.58). A meta-analysis has shown that integrated care model improves patient outcomes, although it is unclear whether colocation is either necessary or sufficient for improving outcomes (Kwan and Nease, 2013). The trial reported in this thesis is therefore the only completed evaluation of 'real life' colocation framework in Indonesia, and among the first worldwide, looking at patient outcomes, with robust experimental design.

The trial found that there are significantly more participants returning for intervention in the WHO mhGAP arm compared to the Specialist arm. It is possible that there is a stronger stigma associated with a mental health consultation with a psychologist than the generic nature of GP consultations. Stigma has been found to be a barrier to help-seeking (Clement et al., 2015) resulting in low demands for mental health services. Seeking help from a Clinical Psychologist requires recognition of one's mental health needs. In comparison, seeking mental health assistance from a GP, especially one that the patient already holds a queue number for, may be deemed more palatable. Separating mental health care from physical health care can entrench isolation and encourage stigma towards those affected (Link and Phelan, 2006, Schulze and Angermeyer, 2003). The provision of mental health care by primary care doctors addresses this isolation and stigma issue to a large extent.

The study finding is a stark contrast with a previous study of patient preferences for mental health service providers conducted in England alongside an effectiveness trial (Ward et al., 2000). The English study found that when given a choice, primary care patients who met the criteria for depression preferred non-directive counselling or cognitive behaviour therapy with a psychologist instead of general practitioner care. Primary care patients were also reluctant to risk being randomly allocated to the general practitioner care. On the other hand, a different study conducted in the primary care setting in India found that patients reported similar levels of trust and perceived experience of quality from both physician and non-physician clinicians (Rao et al., 2013). Similar to the current study, patients were given the option to choose the type of service provider. It should be noted that the study in India examined patients who received care for their physical ailments instead of mental health care, although this was the only other related research available. More in-depth, context-specific and cross-contextual research should be undertaken to understand these differences fully.

5.5 Implications

This trial shows that screening could quickly identify those with an indication of psychiatric morbidity in busy primary care clinics. The GHQ-12 has been established as a satisfactory tool for screening psychiatric morbidity in the Yogyakarta *Puskesmas* setting. The screening procedure has been tested during the pilot and substantive phases of the trial and could be further refined for adoption in Indonesian primary care clinics.

A functional screening procedure is perhaps the quickest way to identify primary care patients at risk of psychiatric disorders. Primary care clinicians may lack confidence in asking questions pertaining to mental health, as described in Chapter 2. Given busy primary care settings and the limitations of time which could be spared for probing patients who might not otherwise express their symptoms verbally, I believe that screening helps strengthen the primary mental health care system. A 'fairly accurate' screening tool like the GHQ-12 in the Indonesian primary care context has an acceptable balance of

sensitivity and specificity, which means primary care clinicians could ask follow-up questions with considerably greater confidence.

At the outset of the trial, there were concerns that the trial aimed to compare the competency of general practitioners in mental health care management against clinical psychologists. Both professions were reluctant to participate, fearing their work contracts could be terminated if their performance was considered sub-par. Mitigation strategies described in Chapter 3 were found to be successful in dealing with clinicians' reluctance. Despite initial concerns that non-specialist may do poorly compared to specialists, both frameworks were found to work equally well in improving patient outcomes. This trial shows that mild to moderate mental health issues could be handled in primary care, echoing previous international research (van Ginneken et al., 2011, Caulfield et al., 2018).

While the adaptation of the WHO mhGAP in Indonesia highlighted the government commitment to mental health care, without a monitoring system to ensure accountability, treatment adherence is unknown, and efficacy not guaranteed. Without a monitoring system in place, perhaps the health system should focus on introducing a screening procedure to assist with the identification of psychiatric morbidity. Moreover, post-hoc analysis of participants' symptoms at baseline, using the CIS-R algorithm to map symptoms to ICD-10 diagnoses found that the majority of participants had symptoms of disorders beyond the scope of the WHO mhGAP protocol. Adherence to the mhGAP protocol means three quarters of current WHO mhGAP arm participants would be dropped out of the trial. Given the remaining stigma surrounding psychology consultations, if adherence to the mhGAP protocol is the approach taken in real-life practice, Treatment Gap would remain enormous.

Arguably, all Indonesian medical graduates would have competency in diagnosing and (at least) initial intervention of all ICD-10 psychiatric diagnoses commonly found in primary care. *Puskesmas* doctors, should therefore be able to recognise and manage these disorders in the first instance, or have a procedure for referral otherwise. This leads to questions regarding the utility of the adapted WHO mhGAP framework in the Indonesian context. As the implementation cost is enormous, the Indonesian Ministry of Health should wisely reconsider the nation-wide scale-up and resist international pressure to take action. The WHO mhGAP framework, despite its adaptation, is a costly exercise which may not be the answer the country was hoping for. A primary focus on screening and early identification, followed by initial intervention by publicly trusted *Puskesmas* doctors, relying on their existing medical competencies, is a less costly and feasible alternative. A second focus on strengthening the referral system for moderate to severe cases, may help reduce the mental health Treatment Gap.

There is a significant need for all clinicians to discuss treatment plans with patients and for patients to be actively involved in its development. All clinicians must inform their patients the of predicted number of sessions, what kind of intervention it would be, what are the key indicators of remission, and a discharge process at the end. Forming a therapeutic alliance with patients is a key determinant of treatment efficacy for psychiatric disorders. While building trust is a challenging exercise, once the therapeutic alliance is established, treatment adherence could significantly improve.

The reluctance of patients to return for intervention or follow-up interview suggests that in the Yogyakarta context, home visit was preferable and should be considered more frequently to improve adherence and fidelity, despite loopholes such as the presence of family members in the vicinity. The health system has additional provision for home visits under the universal health coverage, which supports the proposition of increasing the frequency of home visits. *Puskesmas* receives additional reimbursements from the state insurance system for home visits. While home visits require significantly more time investment, the outcomes may be favourable.

A recent systematic review of the WHO mhGAP evidence from LMICs (Keynejad et al., 2018), highlighted the pressing need for an understanding of contextual challenges in the field, detailed protocols, qualitative studies, as well as randomised controlled trials – all of which have been offered by this trial and studies conducted alongside, for the Indonesian context.

This trial therefore provides potential learning points for other countries, which may not be considered Low or Middle-Income, but have similarly limited resources for mental health services due to an imbalance of supply and demand, such as the UK and Singapore. Stigma towards mental health issues, and by proxy, stigma towards consultations with mental health specialists, is not limited to LMICs. Migrant populations might carry the stigma and lack of psychoeducation with them. In an increasingly globalised world, societies are becoming multi-cultural, and as a result, mental health systems must be prepared to catch those who would otherwise fall through the cracks due to fear of stigma of seeing a mental health specialist, or lack understanding of mental health altogether.

In contexts where the waiting time to see a specialist could result in further detriment to the patient, providing mental health services for mild to moderate conditions within primary care is a clinically effective temporary solution, until the number of specialists reach acceptable levels.

While there are clear arguments for the integration of mental health into primary care, Saraceno et al. (2007) noted the three key barriers to the integration of mental health into primary care. Firstly, the overburdened primary care means that general practitioners may not have the time to provide adequate mental health care. Secondly, primary care physicians do not receive regular supervision and support for mental health care, which may result in inappropriate treatment. Lastly, essential psychotropic medication may not be available. It has been argued that the role of mental health specialists, including psychiatrists, psychologists, and mental health nurses, among others, should transform from service provision to training and supervision (Saraceno et al., 2007).

Provincial and district governments which in Indonesia are responsible for the management of primary care clinics are increasingly interested in implementing the Specialist Co-location model too. Recently,

the governor of Jakarta stated his wish to provide psychology services in the capital province's primary care clinics (Purba, 2017). This requires enormous resources which require additional safeguarding of budgets to prevent corruption, followed by a sharp increase in the number of qualified clinical psychologists interested in primary care work. As the ultimate consumers and beneficiaries, patients' preferences should be considered not only in the development of an effective approach but also when deciding to scale-up the programme across the country.

Given our findings, the systematic roll-out of the WHO mhGAP framework across all Indonesian stateowned primary care signals the government's commitment to improving the mental health system. As Saraceno and colleagues (2007) argued, specialist mental health workforce in low-resource settings should consider training and supervision roles instead, perhaps limiting direct clinical work to severe and persistent cases; whereas task-shifting and sharing, and investing in the community and primary care might be preferable and beneficial.

5.6 Suggestions for Further Research

In detailing the strengths and weaknesses of the trial, information gaps specifically on the relevance of the adapted WHO mhGAP training for *Puskesmas* doctors, its subsequent utility in clinical practice, and the impact of adherence to the framework in terms of the accuracy of diagnosis and improved treatment outcomes remain unaddressed. Future evaluations in the Indonesian context might benefit from addressing these gaps.

Future research should adopt a third treatment arm: *Puskesmas* doctors who had not been trained in the adapted WHO mhGAP. Future research should also explore the accuracy of *Puskesmas* doctors' diagnosis of common mental disorders, compared to a gold standard such as the CIS-R, or the Comprehensive Psychopathological Rating Scale (CPRS).

Although the trial design was relevant to the potential implementation of a screening procedure within primary care setting in Indonesia, and develop a primary mental health system which combines the benefits of both the adapted WHO mhGAP and Specialist Co-location frameworks, high-quality health services and delivery research is required to explore how best to combine available resources and package an implementable procedure.

Geo-cultural context, specifically as the trial took place in rural Java, would have undoubtedly influenced the outcomes of the current trial. While this increases the generalisability of the trial in the Indonesian context, with the majority of Indonesians being ethnic Javanese and living in Java, a large proportion of the population who live outside Java were underrepresented. These are arguably the people who needed the adapted WHO mhGAP framework the most, as there are far too few mental health specialists (psychiatrists or clinical psychologists) living outside Java. Additionally, the power dynamics between clinicians and patients, and especially when the patients also become 'the

researched' remain understudied, especially in Indonesia's primary care context. Replicating this trial in other provinces within Indonesia, with more substantial research funding and longer duration of recruitment might be beneficial for future country-level decision-making. Future trials should also consider social support and social connectivity as a moderating effect influencing patient outcomes.

Additionally, substantial qualitative work should be carried out alongside and as part of future work in order to fully understand preferences, attitudes, socio-cultural and other contextual factors and issues at play. Patient preferences are often disregarded within clinical settings (Allison and Sudore, 2013). Despite this, they are increasingly regarded as key to ensure the development of a mental health system that patients feel comfortable to access and do actually access. An often-neglected perspective, the people coming to the service should be consulted when planning a scale-up of existing services, as ultimately, it is they who will either benefit or not from the service. Unlike market research prior to the roll-out of consumer products, the scale-up of healthcare interventions still tends to be decided top-down, without considering patients' preferences.

5.7 Fieldwork Learning Points

There were several important lessons I gathered from the various fieldwork periods in Indonesia. Most important of all is to maintain records of communications with policymakers so that when inevitable staff turnover occurred, I could continue moving forward. During the trial, the Chief Executive of the Provincial Health Authority was reshuffled to a new position, and the post of Chief Executive was vacant for six months. Additionally, the Head of Medical Services at the Provincial Health Authority was also reshuffled to become the Director of a psychiatric hospital, just after the pilot study.

During the trial, a few stakeholders including a local collaborator, a Head of *Puskesmas*, and administrators of several *Puskesmas* requested financial contributions which were not previously communicated, some of which were beyond the official financial guidelines of *Puskesmas* fees. It seems the local culture did not frown upon such requests, which was a surprise. While I agreed to pay data collection fees according to local guidelines, with the receipt provided, I declined to make any financial contributions to individuals. As a result, our baseline recruitment at one *Puskesmas* had to be cut short.

I also learned to be proactive and prepared for concise impromptu speeches, for longer seminars, and for any visual aids required during the period of the trial. Stakeholders are usually extremely busy and are working on multiple projects, so being clear, concise, and memorable was my adopted strategy.

Finally, I learned that working in real-life settings is very different from working in a lab, in that I have very little control over the context of the trial. Prescribed time frames were, in fact, a guide rather than definite and cultural differences in work ethics could result in misunderstandings. It was imperative to try to remain a motivated realist during the trial.

5.8 Recommendations

Given the capability of the primary care system to manage mild to moderate cases, perhaps existing specialist resources could be rearranged into a hub-and-spoke model. This would reduce healthcare spending associated with employing a clinical psychologist for every clinic, ensure the efficiency of their working time, and improve accountability. From a health systems perspective, the hub-and-spoke model would simplify the delivery of interventions and reduce the requirement of specialist workforce, while improving the utility of Clinical Psychologists' working hours. Clinical psychologists working in a hub could further specialise in key intervention technique and hone their expertise with a subset of clients (e.g. children, geriatric population, juvenile offenders) based on their diagnoses and needs. Upskills training such as the Dialectical Behavioural Therapy for Borderline Personality Disorder, and Trauma-Focused CBT for children and adults who had been abused, and Functional Family Therapy for juvenile delinquents are copyrighted training programmes with established efficacy and accompanying high price tags. Nation-wide training costs could be reduced by sending one clinical psychologist per hub to attend these expensive certifications, while requiring a mandatory work commitment (bond) commensurate to the cost of the training.

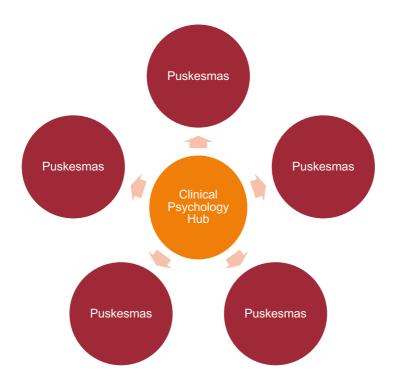


Figure 16. Clinical Psychology Hub in a Hub and Spoke Model

The suggested model facilitates stepped-care arrangements where patients are offered a low-intensity intervention in the first instance, at *Puskesmas* level, with a smaller proportion going on to higher-intensity options at the Clinical Psychology hubs. Those failing to benefit from low-intensity interventions according to some agreed criteria would then continue to the high-intensity intervention.

A collegiate working environment would be beneficial for the morale of clinical psychologists, improve creativity in managing cases through discussions, and increase accountability through supervisions. Regular audits could be performed, which would ensure the timeliness of assessment from the date of referral, appropriate management of conditions, as well as appropriate discharge procedures.

There are currently no existing psychosocial therapy guidelines for psychiatric disorders in Indonesia, like the NICE guidelines in the UK. There is merit in producing evidence-based 'good clinical practice' guidelines to inform clinicians of the appropriate management strategy for psychiatric disorders, given the obvious limitations of the WHO mhGAP manual. It would be even more impactful if the guidelines could be supplemented with empirical evidence from Indonesia. Such guidelines could also assist clinicians in informing their patients of their customised treatment plan, including any step-up care arrangement should they not respond to low-intensity treatment.

Halting current nation-wide implementation of the WHO mhGAP framework is recommended, in light of the limitations of the manual in providing relevant new competencies for primary care doctors. If the week-long training only served to improve primary care doctors' confidence in diagnosing mental disorders among their patients, less costly alternatives should be explored, and perhaps included in the continuing medical education framework for a maximum reach.

There is merit, however, in keeping the delivery of mental health services in primary care. When referrals are made to a secondary mental health service, no appointment is ever made for up to 90% of referrals made (Callahan et al., 2002, Katon, 1995, Kessler and Stafford, 2008). Integrating depression and hypertension treatment has been found to be effective in improving patient outcomes (Bogner and de Vries, 2008), and despite their limitations, both frameworks tested in the trial would make this feasible.

5.9 Conclusion

This thesis achieved its primary aims. The primary care mental health services as part of the Indonesianadapted WHO mhGAP or the Specialist Co-location framework were found to be equally effective in improving patients' clinical outcomes. Given that both frameworks yielded positive patient outcomes, there is no immediate need to increase the absolute number of specialist mental health professionals in community psychiatry (i.e. replicate the specialist framework outside Yogyakarta). The colocation of Clinical Psychologists in primary care requires a larger health budget (manpower costs), which may be a worthwhile investment as the Specialist framework was found to be cost-effective compared to the adapted WHO mhGAP framework.

As most psychologists and psychiatrists in Indonesia reside in large cities, the current systematic rollout of the adapted WHO mhGAP framework might address the need to strengthen non-stigmatising mental health care within community contexts, reflecting the preferences of primary care patients. Indonesian primary care doctors should be equipped to deal with the range of mental disorders presenting in primary care, even without the additional adapted mhGAP training, and therefore further research confirming this should be conducted. Meanwhile, the nation-wide implementation of the adapted mhGAP framework should be halted before the merits of the training are made certain. Various models of integrated care, which optimises the availability of manpower and cost of hiring manpower against community demands, should be tested in Indonesia before a new nation-wide policy is decided.

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7 APPENDICES

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APPENDIX A: ADAPTED WHO MHGAP TRAINING SCHEDULE IN YOGYAKARTA

JADWAL PELATIHAN PENINGKATAN KETERAMPILAN KESWA BAGI PETUGAS KESEHATAN DI PUSKESMAS (DOKTER UMUM)

Training timetable for Add-on Competency Training in Mental Health for Health Workers in Puskesmas (General Practitioners)

HARI (DAY) I	Senin (Monday), 11 April 2016
11.00 – 12.00 WIB	Registrasi dan Makan Siang (Registration and Lunch)
12.00 – 12.30 WIB	Pembukaan (Opening Address)
	Laporan Ketua Panitia (Report from Head of Programme)
	Sambutan Direktur P2MKJN (Welcome from Director of Mental Health)
12.30 – 13.15 WIB	Situasi Terkini Kesehatan Jiwa dan Kebijakan Nasional Kesehatan Jiwa
	2015-2019 (Latest Situation on Mental Health and National Mental Health Policies 2015-2019)
13.15 – 14.15 WIB	ISHOMA (Rest, Prayer, Meal)
14.15 – 14.45 WIB	Pre Test
15.45 – 16.15 WIB	BLC (Background and Learning Content)
16.15 – 17.00 WIB	Deteksi Dini Masalah Kesehatan Jiwa (Early Detection of MH Problems)
17.00 – 17.15 WIB	Break Shalat Ashar + Coffee Break
17.15 – 18.00 WIB	Wawancara Psikiatri (Psychiatric Interviewing)
HARI (DAY) II	Selasa (Tuesday), 12 April 2016
07.30 – 07.45 WIB	Refleksi (Reflection)
07.45 – 09.30 WIB	Gangguan Depresi (Depression)
09.30 – 09.45 WIB	Coffee Break
09.45 – 12.00 WIB	Gangguan Depresi (Depression)
12.00 – 13.00 WIB	ISHOMA (Rest, Prayer, Meal)
13.00 - 14.30 WIB	Gangguan Ansietas (Anxiety)
14.30 – 14.45 WIB	Coffee Break
14.45 – 16.15 WIB	Gangguan Ansietas (Anxiety)
16.15 – 16.30 WIB	Break Shalat Ashar (Break and Afternoon Prayer)
16.30 – 17.30 WIB	Gangguan Perkembangan dan Perilaku pada Anak (Child and adolescent mental and behavioural disorders)
HARI (DAY) III	Rabu (Wednesday), 13 April 2016
07.30 - 07.45 WIB	Refleksi (Reflection)

07.45 - 09.15 WIB	Gangguan Psikotik (Psychoses)
09.15 – 09.30 WIB	Coffee Break
09.30 – 12.00 WIB	Gangguan Psikotik (Psychoses)
12.00 – 13.00 WIB	ISHOMA (Rest, Prayer, Meal)
13.00 – 14.30 WIB	Gangguan Demensia pada Lansia (Dementia)
14.30 – 14.45 WIB	Coffee Break
14.45 – 16.15 WIB	Gangguan Demensia pada Lansia (Dementia)
HARI (DAY) IV	Kamis (Thursday), 14 April 2016
07.30 - 07.45 WIB	Refleksi (Reflection)
07.45 - 10.00 WIB	Kegawatdaruratan Psikiatrik (Psychiatric Emergency)
10.00 - 10.15 WIB	Coffee Break
10.15 - 12.00 WIB	Kegawatdaruratan Psikiatrik (Psychiatric Emergency)
12.00 – 13.00 WIB	ISHOMA (Rest, Prayer, Meal)
13.00 - 15.00 WIB	Pelaksanaan Sistem Rujukan (Referral System)
15.00 – 15.15 WIB	Coffee Break
15.15 – 16.30 WIB	Pencatatan dan Pelaporan (Recording and Reporting)
16.30 – 17.00 WIB	Penjelasan Praktek Lapangan (Field Practice Briefing)
17.00 – 17.30 WIB	Rencana Tindak Lanjut (RTL) (Management Plan)
HARI (DAY) V	Jumat (Friday), 15 April 2016
07.00 - 07.15 WIB	Refleksi (Reflection)
07.15 - 07.45 WIB	Menuju tempat praktek lapangan (Head to Field Practice)
07.45 - 08.00 WIB	Persiapan praktik lapangan (Field Practice Preparation)
08.00 – 11.00 WIB	Praktik Lapangan (Field Practice)
11.00 – 11.30 WIB	Kembali ke tempat pelatihan
11.30 – 13.00 WIB	ISHOMA (Rest, Prayer, Meal)
13.00 - 14.00 WIB	Diskusi Kelompok Hasil PKL (Group Discussion of Field Practice Results)
14.00 - 14.15 WIB	Coffee Break
14.15 - 15.45 WIB	Presentasi Hasil Diskusi Kelompok dan Diskusi Pleno (Group Presentation)
15.45 – 16.15 WIB	Post Test
16.15 - 16.30 WIB	Simpulan dan Penutupan (Conclusion and Closing Remarks)
16.30 – 17.30 WIB	Penyelesaian administrasi (Administrative Matters)

JADWAL PELATIHAN PENINGKATAN KETERAMPILAN KESWA BAGI PETUGAS KESEHATAN DI PUSKESMAS (PERAWAT)

Training timetable for Add-on Competency Training in Mental Health for Health Workers in Puskesmas (Nurses)

HARI (DAY) I Senin (Monday), 11 April 2016

11.00 - 12.00 WIB	Registrasi dan Makan Siang (Registration and Lunch)	
12.00 - 12.30 WIB	Pembukaan (Opening Address)	
	Laporan Ketua Panitia (Report from Head of Programme)	
	Sambutan Direktur P2MKJN (Welcome from Director of Mental Health)	
12.30 – 13.15 WIB	Situasi Terkini Kesehatan Jiwa dan Kebijakan Nasional Kesehatan Jiwa	
	2015-2019 (Latest Situation on Mental Health and National Mental Health Policies 2015-2019)	
13.15 – 14.15 WIB	ISHOMA (Rest, Prayer, Meal)	
$14.15 - 14.45 \ WIB$	Pre Test	
15.45 – 16.15 WIB	BLC (Background and Learning Content)	
16.15 – 17.00 WIB	Deteksi Dini Masalah Kesehatan Jiwa (Early Detection of MH Problems)	
17.00 – 17.15 WIB	Break Shalat Ashar + Coffee Break	
17.15 – 18.00 WIB	Komunikasi dalam Pelayanan Keperawatan Jiwa (Communication in Mental Health Nursing)	
HARI (DAY) II	Selasa (Tuesday), 12 April 2016	
07.30 – 07.45 WIB	Refleksi (Reflection)	
07.45 – 09.30 WIB	Komunikasi dalam Pelayanan Keperawatan Jiwa (Communication in Mental Health Nursing)	
$09.30 - 09.45 \ \mathrm{WIB}$	Coffee Break	
$09.45 - 12.00 \ WIB$	Asuhan Keperawatan Gangguan Depresi (Nursing Care for Depression)	
12.00 - 13.00 WIB	ISHOMA (Rest, Prayer, Meal)	
13.00 - 14.30 WIB	Asuhan Keperawatan Gangguan Depresi (Nursing Care for Depression)	
14.30 - 14.45 WIB	Coffee Break	
14.45 – 16.15 WIB	Asuhan Keperawatan Gangguan Ansietas (Nursing Care for Anxiety)	
16.15 – 16.30 WIB	Break Shalat Ashar	
16.30 – 17.30 WIB	Asuhan Keperawatan Gangguan Ansietas (Nursing Care for Anxiety)	
HARI (DAY) III	Rabu (Wednesday), 13 April 2016	
07.30 - 07.45 WIB	Refleksi (Reflection)	
$07.45 - 09.15 \ WIB$	Asuhan Keperawatan Gangguan Psikotik (Nursing Care for Psychoses)	
$09.15 - 09.30 \ \mathrm{WIB}$	Coffee Break	
09.30 - 12.00 WIB	Asuhan Keperawatan Gangguan Psikotik (Nursing Care for Psychoses)	
Efek Samping Antipsil psychiatric medications	kotik dan Obat Psikiatrik Lainnya (Side effects of antipsychotics and other)	
12.00 – 13.00 WIB	ISHOMA (Rest, Prayer, Meal)	
13.00 – 14.30 WIB Pada Anak (Nursing car	Asuhan Keperawatan pada Gangguan Perkembangan & Gangguan Perilaku re for Child and adolescent mental and behavioural disorders)	
14.30 – 14.45 WIB	Coffee Break	

Asuhan Keperawatan Gangguan Psikotik (Nursing Care for Psychoses)

14.45 – 15.45 WIB

15.45 – 17.00 WIB	Asuhan Keperawatan pada Gangguan Demensia pada Lansia (Nursing care for
Dementia)	

HARI (DAY) IV	Kamis (Thursday), 14 April 2016
$07.30 - 07.45 \ \mathrm{WIB}$	Refleksi (Reflection)
$07.45 - 10.00 \ WIB$	Kegawatdaruratan Psikiatrik (Psychiatric Emergency)
10.00 - 10.15 WIB	Coffee Break
10.15 - 12.00 WIB	Kegawatdaruratan Psikiatrik (Psychiatric Emergency)
12.00 - 13.00 WIB	ISHOMA (Rest, Prayer, Meal)
13.00 - 15.00 WIB	Pelaksanaan Sistem Rujukan (Referral System)
15.00 – 15.15 WIB	Coffee Break
15.15 – 16.30 WIB	Pencatatan dan Pelaporan (Recording and Reporting)
16.30 – 17.00 WIB	Penjelasan Praktek Lapangan (Field Practice Briefing)
17.00 – 17.30 WIB	Rencana Tindak Lanjut (RTL) (Management Plan)
HARI (DAY) V	Jumat (Friday), 15 April 2016
07.00 - 07.15 WIB	Refleksi (Reflection)
$07.15 - 07.45 \ WIB$	Menuju tempat praktek lapangan (Head to Field Practice)
$07.45 - 08.00 \ WIB$	Persiapan praktik lapangan (Field Practice Preparation)
08.00 – 11.00 WIB	Praktik Lapangan (Field Practice)
11.00 – 11.30 WIB	Kembali ke tempat pelatihan
11.30 – 13.00 WIB	ISHOMA (Rest, Prayer, Meal)
13.00 - 14.00 WIB	Diskusi Kelompok Hasil PKL (Group Discussion of Field Practice Results)
14.00 - 14.15 WIB	Coffee Break
14.15 – 15.45 WIB	Presentasi Hasil Diskusi Kelompok dan Diskusi Pleno (Group Presentation)
15.45 – 16.15 WIB	Post Test
16.15 – 16.30 WIB	Simpulan dan Penutupan (Conclusion and Closing Remarks)
16.30 – 17.30 WIB	Penyelesaian administrasi (Administrative Matters)

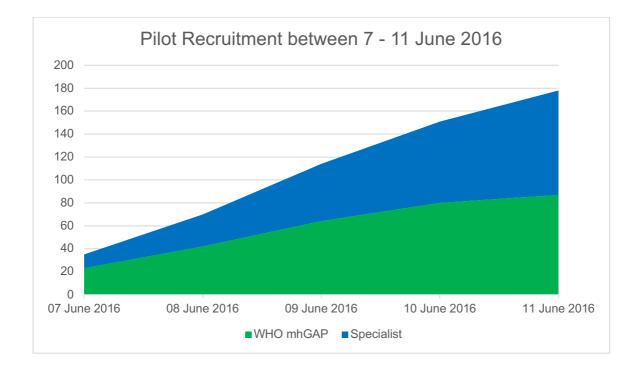
APPENDIX B: RANDOMISED CLUSTERS AND CLINICIANS INVOLVED IN THE TRIAL

No.	WHO mhGAP Cluster	District	General Practitioner	Mobile Phone Number
1	SEYEGAN	Sleman	dr. Dharmawan Lingga A	0818 721 336
2	NGEMPLAK I	Sleman	dr. Nurul Agus D	0853 9732 4393
3	NGAGLIK II	Sleman	dr. Adriana	0856 4363 6660
4	UMBUL HARJO I	Kota	dr. Alissyah	0853 6991 8700
5	KOTA GEDE I	Kota	dr. Liza D. Anjumi	0818 508 638
6	GONDOMANAN	Kota	dr. Deo Hadi Nanda	0818 0405 0278
7	RONGKOP	Gunung Kidul	dr. M. Muslih	0813 2929 3838
8	KARANGMOJO II	Gunung Kidul	dr. Nuri Cahyawati	0877 3823 7937
9	JETIS II	Bantul	dr. Yulia Dewi Irawati	0812 1550 0707
10	SEDAYU II	Bantul	dr. Sri Rahayu	0812 2699 811
11	SRANDAKAN	Bantul	dr. Fifi Sumarwati	0812 2595 9400
12	TEMON I	Kulon Progo	dr. Fitri Nurkhamidah	0815 7854 8608
13	WATES	Kulon Progo	dr. Dian Monika Sharie	0813 2847 1675
14	KALIBAWANG	Kulon Progo	dr. Ria Fitriana S.	0857 2929 2575
No.	Specialist Cluster	District	Clinical Psychologist	Mobile Phone Number
1	MOYUDAN	Sleman	Nyimas Rafika	0812 2710 1182
2	MINGGIR	Sleman	Fahrunnisa	0856 4330 0651
3	GODEAN II	Sleman	Ratih Ary Nurani	0857 1179 9904
4	GAMPING I	Sleman	Setyoningrum	0815 7917 590

5	MLATI II	Sleman	Berta Devi Aryani	0877 3939 2818 / 0856 286 3101
6	DEPOK II	Sleman	Elly Ervinawati	0813 2283 2077
7	BERBAH	Sleman	Liawati	0811 266 319 / 0818 0431 4900
8	KALASAN	Sleman	Herlin Utari	0815 6843 3282
9	SLEMAN	Sleman	Titik Adianingsih	0813 2822 9998
10	KOTA GEDE II	Kota	Firra Berlinawati	0818 0434 2407
11	DANUREJAN I	Kota	Sarita M & Mega D	0819 1552 4913
12	DANUREJAN II	Kota	Salwa Usrati	0818 0362 1172
13	NGAMPILAN	Kota	Eka Maulidya Bastra	0815 2424 9938
14	JETIS	Kota	Ermin Emillia	0818 0269 2949

APPENDIX C: PILOT RECRUITMENT GRAPH

During the pilot recruitment period, 2-9% of daily adult attendees from 27 Puskesmas agreed to additional psychiatric interviewing. At the end of the recruitment week (5 days), 178 patients agreed to additional psychiatric interviewing.



APPENDIX D: UNIVERSITY OF CAMBRIDGE ETHICS

Karen Douglas Secretary

Dr Tine Van Bortel Department of Public Health and Primary Care Forvie Site Robinson Way Cambridge CB2 0SR



CAMBRIDGE PSYCHOLOGY RESEARCH ETHICS COMMITTEE

Application No: PRE.2015.108

15 December 2015

Dear Dr Van Bortel

Evaluating the clinical- and cost-effectiveness of two primary mental health service frameworks in Yoyakarta, Indonesia

The Cambridge Psychology Research Ethics Committee has given ethical approval to your research project: Evaluating the clinical- and cost-effectiveness of two primary mental health service frameworks in Yoyakarta, Indonesia, as set out in your application dated 8 November 2015.

The Committee attaches certain standard conditions to all ethical approvals. These are:

- (a) that if the staff conducting the research should change, any new staff should read the application submitted to the Committee for ethical approval and this letter (and any subsequent letter concerning this application for ethical approval);
- (b) that if the procedures used in the research project should change or the project itself should be changed, you should consider whether it is necessary to submit a further application for any modified or additional procedures to be approved;
- (c) that if the employment or departmental affiliation of the staff should change, you should notify us of that fact.

Members of the Committee also ask that you inform them should you encounter any unexpected ethical issues.

If you would let us know that you are able to accept these conditions, we will record that you have been given ethical approval.

Please note that there have been changes to the procedures regarding amendments. Full details are given on the REC website.

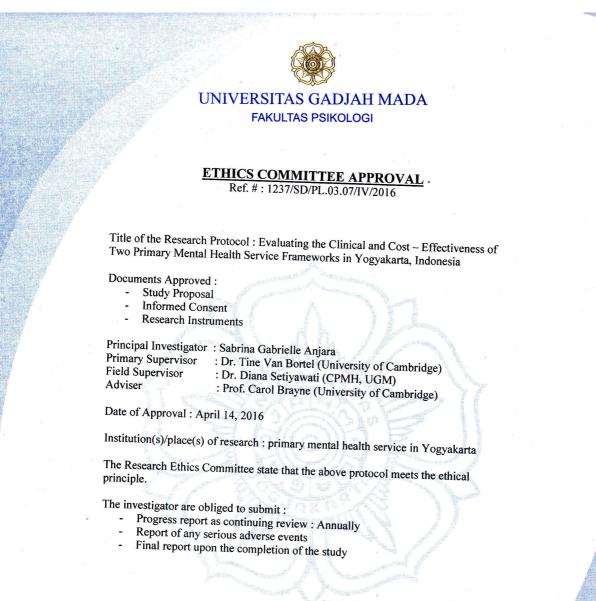
Yours sincerely

K S Douglas

cc Sabrina Anjara

17 Mill Lane Cambridge CB2 1RX Telephone: 01223 766894 Fax: 01223 332355 E-mail: mb422@admin.cam.ac.uk

APPENDIX E: UNIVERSITAS GADJAH MADA ETHICS



Yogyakarta, 14 April 2016 Vice Dean for Research and Chairman of Research Ethics

ommittee, Proto Drs. Subandi, MA, PhD

JI. Sosio Humaniora No. 1, Bulaksumur, Yogyakarta 55281, Indonesia, Telp. +62 274 550435, Faks. +62 274 550436 E-mail: fpsi@ugm.ac.id, Website : www.psikologi.ugm.ac.id

APPENDIX F: UNIVERSITY OF CAMBRIDGE TRIAL INSURANCE



Ross Elliott Insurance Adviser Our Ref: 609/M/C/1510

Dr Tine Van Bortel Department of Public Health and Primary Care University of Cambridge

5th November 2015

Dear Dr Van Bortel

Evaluating the clinical and cost-effectiveness of two primary mental health service frameworks in Yogyakarta, Indonesia

I confirm that this research study is covered by the University's Public Liability and Professional Indemnity insurance policies.

Evidence of insurance is attached in the form of letters from the University's insurance brokers. These insurance policies are renewed annually on 1st August and broker letters confirming insurance for new insurance years can be obtained from the University insurance office from the third week in August each year.

Please notify me of any amendments to this study so that I can ensure that we have appropriate insurance in place.

Yours sincerely

8.8. V. Hollamby

Ross Elliott

Greenwich House Madingley Rise, Madingley Road Cambridge CB3 0TX Tel: +44 (0) 1223 339659 Fax: +44 (0) 1223 765988 Email: @admin.cam.ac.uk www.cam.ac.uk

APPENDIX G: YOGYAKARTA PROVINCE APPROVAL TO CONDUCT RESEARCH

operator2@yahoo.com PEMERINTAH DAERAH DAERAH ISTIMEWA YOGYAKARTA SEKRETARIAT DAERAH Kompleks Kepatihan, Danurejan, Telepon (0274) 562811 - 562814 (Hunting) YOGYAKARTA 55213 SURAT KETERANGAN / IJIN 070/REG/V/625/5/2016 Membaca Surat : KEPALA CMPH Nomor : 087/B/CPMH/V/2016 Tanggal : 26 MEI 2016 Perihal **IJIN PENELITIAN/RISET** Mengingat : 1. Peraturan Pemerintah Nomor 41 Tahun 2006, tentang Perizinan bagi Perguruan Tinggi Asing, Lembaga Penelitian dan Pengembangan Asing, Badan Usaha Asing dan Orang Asing dalam melakukan Kegitan Penelitian dan Pengembangan di Indonesia: 2. Peraturan Menteri Dalam Negeri Nomor 20 Tahun 2011, tentang Pedoman Penelitian dan Pengembangan di Lingkungan Kementrian Dalam Negeri dan Pemerintah Daerah; 3. Peraturan Gubernur Daerah Istimewa Yogyakarta Nomor 37 Tahun 2008, tentang Rincian Tugas dan Fungsi Satuan Organisasi di Lingkungan Sekretariat Daerah dan Sekretariat Dewan Perwakilan Rakyat Daerah. 4. Peraturan Gubemur Daerah Istimewa Yogyakarta Nomor 18 Tahun 2009 tentang Pedoman Pelayanan Perizinan, Rekomendasi Pelaksanaan Survei, Penelitian, Pendataan, Pengembangan, Pengkajian, dan Studi Lapangan di Daerah Istimewa Yogyakarta. DIIJINKAN untuk melakukan kegiatan survei/penelitian/pendataan/pengembangan/pengkajian/studi lapangan kepada: Nama SABRINA GABRIELLE ANJARA NIP/NIM : -Alamat FAKULTAS PSIKOLOGI, CENTER FOR PUBLIC MENTAL HEALTH, UNIVERSITAS GADJAH MADA EVALUASI EFEKTIVITAS KLINIS DAN BIAYA PELAYANAN KESEHATAN JIWA Judul PUSKESMAS DI YOGYAKARTA, INDONESIA Lokasi DINAS KESEHATAN DIY Waktu : 27 MEI 2016 s/d 27 AGUSTUS 2016 Dengan Ketentuan 1. Menyerahkan surat keterangan/ijin survei/penelitian/pendataan/pengembangan/pengkajian/studi lapangan *) dari Pemerintah Daerah DIY kepada Bupati/Walikota melalui institusi yang berwenang mengeluarkan ijin dimaksud; 2. Menyerahkan soft copy hasil penelitiannya baik kepada Gubernur Daerah Istimewa Yogyakarta melalui Biro Administrasi Pembangunan Setda DIY dalam compact disk (CD) maupun mengunggah (upload) melalui website adbang jogjaprov.go.id dan menunjukkan cetakan asli yang sudah disahkan dan dibubuhi cap institusi; 3. Ijin ini hanya dipergunakan untuk keperluan ilmiah, dan pemegang ijin wajib mentaati ketentuan yang berlaku di lokasi kegiatan; 4. Ijin penelitian dapat diperpanjang maksimal 2 (dua) kali dengan menunjukkan surat ini kembali sebelum berakhir waktunya setelah mengajukan perpanjangan melalui website adbang.jogjaprov.go.id; 5. Ijin yang diberikan dapat dibatalkan sewaktu-waktu apabila pemegang ijin ini tidak memenuhi ketentuan yang berlaku. Dikeluarkan di Yogyakarta Pada tanggal 27 MEI 2016 A.n Sekretaris Daerah Asisten Perekonomian dan Pembangunan Ub Kepala Biro Administrasi Pembangunan RINTAH BIRO ADM PEMBANGUN E Drs. Tri Mulyono, MM NIP 19620830 198903 1 006 MEWAY Tembusan 1. GUBERNUR DAERAH ISTIMEWA YOGYAKARTA (SEBAGAI LAPORAN) WALIKOTA YOGYAKARTA C.Q DINAS PERIJINAN KOTA YOGYAKARTA 2. 3

- **BUPATI BANTUL C.Q BAPPEDA BANTUL**
- BUPATI SLEMAN C.Q KA. BAKESBANGLINMAS SLEMAN 4.
- 5. BUPATI GUNUNGKIDUL C.Q KPPTSP GUNUNGKIDUL
- BUPATI KULON PROGO C.Q KPT KULON PROGO 6.
- DINAS KESEHATAN DIY 7.
- KEPALA CMPH, UNIVERSITAS GADJAH MADA 8
- YANG BERSANGKUTAN 9.

APPENDIX H: SCREENING QUESTIONNAIRE

KUESIONER KESEHATAN	S:	-	+	Tensi:	/	ID:
				/		

Jawablah semua pertanyaan dengan <u>melingkari</u> jawaban yang paling sesuai dengan Anda. Kami ingin mengetahui tentang keluhan yang dialami sekarang atau akhir-akhir ini, bukan di masa lalu. Kami mohon Anda menjawab semua pertanyaan. **Contoh** :

S dapat XXXXXXXX XXXXX XXXXX Lebih baik dari biasa dari dari biasa
--

Ap	akah Anda akhir-akhir ini :				
S1	Dapat berkonsentrasi pada apa pun yang Anda kerjakan?	LEBIH	BIASA	KURANG	SANGAT KURANG
S2	Sulit tidur karena khawatir?	TIDAK	TIDAK LEBIH	LEBIH DARI BIASA	SANGAT LEBIH
S3	Merasa berperan dalam berbagai hal yang bermanfaat?	LEBIH	BIASA	KURANG	SANGAT KURANG
S4	Merasa mampu untuk membuat suatu keputusan?	LEBIH	BIASA	KURANG	SANGAT KURANG
S5	Merasa <u>terus menerus</u> di bawah tekanan?	TIDAK	BIASA	LEBIH DARI BIASA	SANGAT LEBIH
S6	Merasa tidak sanggup mengatasi kesulitan –kesulitan Anda?	TIDAK	BIASA	LEBH DARI BIASA	SANGAT LEBIH
S7	Dapat menikmati aktivitas kegiatan sehari-hari?	LEBIH	BIASA	KURANG	SANGAT KURANG
S 8	Mampu menanggung masalah-masalah Anda?	LEBIH	BIASA	KURANG	SANGAT KURANG
S9	Merasa tidak bahagia dan tertekan?	TIDAK	TIDAK LEBIH	LEBIH DARI BIASA	SANGAT LEBIH
S10	Kehilangan kepercayaan diri?	TIDAK	TIDAK LEBIH	LEBIH DARI BIASA	SANGAT LEBIH
S11	Berpikir bahwa diri Anda tidak berguna?	TIDAK	TIDAK LEBIH	LEBIH DARI BIASA	SANGAT LEBIH
S12	Setelah mempertimbangkan hal di atas, merasa cukup bahagia?	LEBIH	BIASA	KURANG	SANGAT KURANG

D	1.1. Tanggal Lahir:	1.2. Jenis Kelar	nin: (lingkari)
	(tanggal)/(bulan)/(tahun)	1. Perempuan	2. Laki-laki
	1.3. Status pernikahan: (lingkari)	1.4. Suku:	1.5. Tempat Lahir:
	1. Belum menikah 2. Menikah 3. Pisah 4. Cerai 5. Cerai Mati		
	1.6. Bahasa sehari-hari: (lingkari)		1
	1. Bahasa Indonesia 2. Bahasa Jawa (lancar B. Indonesia) 3	. Bahasa Jawa (tidak	lancar B. Indonesia)
	1.7. Pendidikan Terakhir: (lingkari)	1.9. Diagnosa (diis	si oleh dokter):
	1. SD 2. SMP 3. SMA 4. D3 5. S1 6. Lainnya		
	2.1. Tempat tinggal anda: (lingkari)		
	1. Tinggal sendiri 2. Bersama pasangan 3. Bersama kerabat	4. Bersama orang	atua (kanahat
	3.1. Status pekerjaan Anda: (<i>lingkari</i>)	4. Dersama oran	g tua / Kerabat
	1. Karyawan/wirausaha 2. Sukarelawan 3. Tidak Bekerja 4. Pelajar		
	3.2. Kalau bekerja:	3.3. Penghasilan b	ulanan:
	Pekerjaan:		
	4.1. Pelayanan kesehatan dalam <u>6 bulan</u> terakhir: (lingkari)	4.2. Apakah Anda:	: (lingkari)
	1. Menginap di Rumah Sakit: Ya / Tidak	1. Kencing Manis:	Ya / Tidak
	2. Rawat jalan di Rumah Sakit: Ya / Tidak	2. Darah Tinggi:	Ya / Tidak
	3. Ke Puskesmas (selain hari ini): Ya / Tidak	Terim	a kasih!

APPENDIX I: INFORMATION SHEET

LEMBAR INFORMASI PESERTA PENELITIAN



No Referensi Komite Etik University of Cambridge: PRE.2015.108 No Referensi Komite Etik Universitas Gadjah Mada:1237/SD/PL.03.07/IV/2016

ANDA BOLEH SIMPAN LEMBAR INFORMASI INI

Judul penelitian: Evaluasi efektivitas pelayanan kesehatan di Puskesmas DI Yogyakarta, Indonesia

Jika Anda berusia di atas 18 tahun dan saat ini berobat di puskesmas, Anda diundang untuk berpartisipasi dalam penelitian ini. Mohon luangkan waktu untuk membaca keterangan di bawah dengan teliti untuk mengetahui lebih dalam mengapa penelitian ini dilakukan dan bentuk keterlibatan Anda. Anda boleh diskusi dengan orang lain jika perlu. Silakan bertanya kepada kami jika ada hal-hal yang kurang jelas atau jika Anda ingin mendapatkan informasi lebih lanjut.

- Penelitian ini adalah kajian guna pelayanan kesehatan di puskesmas. Penelitian ini diharapkan dapat membantu para pembuat kebijakan di Kementerian Kesehatan dalam membuat peraturan peraturan kesehatan.
- Jika Anda memutuskan untuk ikut serta, Anda akan diminta untuk menandatangani lembar persetujuan. Setelah itu, Anda akan diminta untuk mengisi dua kuesioner (kurang lebih 10 menit). Jika ada pertanyaan yang Anda tidak ingin menjawab, boleh dibiarkan kosong.
- Selanjutnya, Anda akan bertemu petugas kesehatan yang akan bertanya lebih lanjut mengenai pengalaman Anda. Beberapa pertanyaan mungkin sensitif bagi Anda. Tidak masalah jika Anda tidak ingin menjawab pertanyaan tersebut.
- Petugas kesehatan akan meminta informasi nomor telepon atau ponsel Anda supaya Anda bisa diingatkan untuk kembali untuk cek lanjutan 6 bulan dari sekarang.
- Informasi pribadi yang bisa dilacak kembali kepada Anda tidak akan diketahui orang lain selain petugas kesehatan Anda dan Tim Peneliti.
- Anda dapat menghubungi peneliti untuk meminta salinan dari laporan hasil akhir penelitian (akan selesai pada bulan September 2018): <u>sga29@medschl.cam.ac.uk</u>

Anda bebas memutuskan untuk terlibat dalam penelitian ini atau tidak. Jika Anda memutuskan untuk terlibat, Anda tetap bebas untuk mundur dari penelitian ini kapan pun tanpa perlu memberikan alasan apa pun. Jika Anda merasa tidak nyaman karena penelitian ini, Anda dapat menghubungi University of Cambridge melalui kontak di bawah ini untuk informasi dan saran lebih lanjut:

Sabrina Anjara : <u>sga29@medschl.cam.ac.uk (</u>+44 7397312299) Tine Van Bortel: <u>tv250@medschl.cam.ac.uk</u>

Jika Anda memerlukan perhatian medis segera oleh karena pertanyaan – pertanyaan di kuesioner atau selama wawancara, tolong informasikan petugas kesehatan yang akan merujuk Anda ke rumah sakit terdekat. Terima kasih untuk perhatian dan kesediaan Anda.



INFORMATION SHEET FOR PARTICIPANTS

University of Cambridge Research Ethics Committee Ref: PRE.2015.108 Universitas Gadjah Mada Research Ethics Committee Ref: 1237/SD/PL.03/07/IV/2016

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Evaluating the clinical and cost-effectiveness of two primary mental health service frameworks in Yogyakarta, Indonesia

If you are between 18 and 64 years old and receiving treatment in a primary care facility (*puskesmas*), you are invited to take part in this doctoral research project. Please take time to read the following information carefully to understand why the research is being done and what your participation will involve. You can discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

- You will participate in a pioneering study looking at the clinical and cost-effectiveness of two different mental health service frameworks in a primary care setting. The study will shed some light on the value of primary mental health service in Indonesia: information which is not readily available. The study is expected to help policy makers in producing future regulations beneficial for people with psychiatric disorders.
- If you do decide to take part, you will be given this information sheet to keep and be asked to sign a
 consent form. Following that, you will be given a survey that takes approximately 30 minutes to
 complete.
- After the survey, you will meet a health worker who will ask you further questions about your experiences. You may find some of the questions sensitive. It is okay if you do not want to answer some questions.
- You will be asked by the service provider to provide your name, identity card number, and any other information that can let your service provider follow-up on your experiences 6 months and 12 months from now.
- Identifying information is kept only by your service providers. The researchers will not be able to identify
 you as a respondent.
- The consent form with your signature on it will not be stored together with the survey or the service provider's record.
- This study will hopefully enable us to compare two mental health service frameworks. You are welcome
 to request for a copy of the final report (due out in September 2018) by contacting the researcher at
 sga29@medschl.cam.ac.uk

It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw at any time and without giving a reason.

If this study has harmed you in any way you can contact University of Cambridge using the details below for further advice and information:

Sabrina Anjara sga29@medschl.cam.ac.uk +44 7475 494866

Tine Van Bortel tv250@medschl.cam.ac.uk

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APPENDIX J: CONSENT FORM

UNIVERSITY OF	ID Puskesmas:
LEMBAR PERSETUJUAN KEIKUTSERTAAN PENELITIAN	Nomor Urut:
Mohon tanda tangan di bawah setelah Anda membaca lembar informasi dan/atau mendengarkan penjelasan mengenai penelitian ini.	No. Rekam Medis:
Judul penelitian: Evaluasi efektivitas pelayanan kesehatan jiwa di Puskesmas D	Yogyakarta
No. Referensi Komite Etik University of Cambridge: PRE.2015.108 No. Referensi Komite Etik Universitas Gadjah Mada: 1237/SD/PL.03.07/IV/2016 Izin Pemda Provinsi Daerah Istimewa Yogyakarta: 070/REG/V/152/10/2016	
Terimakasih telah mempertimbangkan untuk terlibat dalam penelitian ini. Asister menjelaskan prosedur penelitian ini kepada Anda sebelum Anda memutuskan unt Anda memiliki pertanyaan setelah membaca lembar informasi atau mendengarkan p penelitian ini, silakan bertanya kepada asisten penelitian sebelum Anda me bergabung atau tidak. Anda dapat menyimpan salinan lembar informasi sebagai pan	uk ikut serta. Jika enjelasan tentang emutuskan untuk
	Silakan beri tanda centang atau inisial
 Saya paham bahwa jika kapanpun saya memutuskan untuk mundur dari per ini, saya dapat memberitahu pihak peneliti dan langsung mundur dari peneli tanpa memberikan alasan apapun. 	
 Saya setuju bahwa informasi pribadi saya akan digunakan sesuai dengan yang telah diberikan kepada saya. Saya paham bahwa pengelolaan informasi saya akan mengikuti undang-undang perlindungan data pribadi. 	
Pernyataan pasien:	
Saya (nama pasien) setuju bahwa saya telah mendapat penjelasan yang memuaskan mengenai penelitia dan saya setuju untuk ikut serta dalam penelitian tersebut. Saya telah membaca ca lembar informasi tentang penelitian ini, dan paham mengenai penelitian ini.	
Tanda tangan: Tanggal: Desem	ıber 2016
Pernyataan asisten penelitian:	
Saya (nama asisten) menyatakan bahwa saya telah menjelaskan dasar, keperluan, dan (jika ada) ker penelitian ini kepada peserta penelitian.	nungkinan resiko
Tanda tangan: Tanggal: Deser	nber 2016

CONCENT		PARTICIPANTS		OTUDICO
LUNSENT	EURIVI EUR	PARTILIPANTS	IN RESEARCH	SHUDES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

UNIVERSITY OF

Please tick or initial

Title of Study: Evaluating the clinical and cost-effectiveness of two primary mental health service frameworks in Yogyakarta, Indonesia

University of Cambridge Research Ethics Committee Ref: PRE.2015.108 Universitas Gadjah Mada Research Ethics Committee Ref: 1237/SD/PL.03/07/IV/2016

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the service provider before you decide whether to join in. You will be given a copy of the Information Sheet to keep and refer to at any time.

I understand that if I decide at any time during the research that I no longer wish
to participate in this project, I can notify the researchers involved and withdraw
from it immediately without giving any reason.

 I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the UK Data Protection Act 1998.

Participant's Statement:

1

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Signed

Date

Service Provider's Statement:

L.

Confirm that I have carefully	xplained the nature, demands and any foreseeable risks (where
applicable) of the proposed i	search to the participant.
Signed	Date

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APPENDIX K: QUESTIONNAIRE BOOKLET

SURVEY PESERTA PENELITIAN

Kuesioner ini berisi pertanyaan tentang <u>kesulitan-kesulitan yang dihadapi berkaitan dengan masalah kesehatan</u>. Masalah kesehatan yang dimaksud mencakup penyakit, gangguan kesehatan yang dapat berlangsung sebentar atau lama, cedera, masalah mental atau emosional, dan masalah yang berkaitan dengan alkohol maupun obat-obatan terlarang.

Pikirkan tentang kondisi Anda dalam <u>30 hari terakhir</u> dan jawablah pertanyaan-pertanyaan di bawah ini, pikirkan seberapa berat kesulitan yang Anda alami ketika melakukan aktifitas berikut ini. Untuk setiap pertanyaan, silakan lingkari <u>satu</u> saja respon yang sesuai.

	Dalam <u>30 hari terakhir</u> , seberapa besar <u>kesulitan</u> yang anda hadapi ketika: MEMAHAMI DAN BERKOMUNIKASI					
Q1.1	<u>Berkonsentrasi</u> dan melakukan sesuatu selama <u>sepuluh menit</u> ?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q1.2	Mengingat untuk melakukan hal penting?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q1.3	Menganalisa dan mencari solusi masalah di kehidupan sehari-hari?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q1.4	<u>Mempelajari</u> <u>hal baru</u> , misalnya belajar cara pergi ke tempat baru?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q1.5	<u>Secara umum memahami</u> apa yang dikatakan oleh orang lain?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q1.6	Memulai dan melanjutkan percakapan?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
BERC	GERAK					
Q2.1	<u>Berdiri</u> untuk <u>waktu yang lama</u> , misalnya 30 menit?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q2.2	Berdiri dari duduk?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q2.3	Berjalan-jalan di dalam rumah?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q2.4	Keluar rumah?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q2.5	Berjalan jauh, misalnya sejauh satu KM?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
MERA	AWAT DIRI					
Q3.1	Membersihkan seluruh badan anda?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q3.2	Memakai baju?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q3.3	Makan?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q4.4	Tinggal sendiri selama beberapa hari?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
BERG	AUL DENGAN ORANG LAIN					
Q4.1	Berurusan dengan orang lain yang tidak Anda kenal?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa

Q4.2	Menjaga hubungan pertemanan?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q4.3	<u>Bergaul</u> dengan orang-orang yang <u>dekat</u> dengan Anda?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q4.4	Mencari teman baru?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q4.5	Mempunyai hubungan romantis?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
WEGI						
	ATAN SEHARI-HARI Melakukan pekerjaan rumah yang	Tidak ada	Dingon	Sodang	Porat	Ekstrim atau
Q5.1	menjadi tanggung jawab Anda?	Пакаца	Ringan	Sedang	Berat	tidak bisa
Q5.2	Melakukan pekerjaan-pekerjaan rumah yang penting <u>dengan baik</u> ?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q5.3	<u>Menyelesaikan</u> pekerjaan rumah yang perlu anda lakukan?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q5.4	Menyelesaikan pekerjaan rumah <u>secepat</u> <u>mungkin</u> ?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Liles	Ande beleenie (dikenen tidele dikenen -	uinen eek e)	atou ao	dana ha	realizata	h silahan isi
	Anda bekerja (dibavar. tidak dibayar, v n yaan nomor Q5.5 - Q5.8 berikut. Jika tidal					
Q5.5	Mengerjakan keiatan sehari-hari di sekolah/kantor?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q5.6	Mengerjakan tugas-tugas penting di sekolah/kantor <u>dengan baik</u> ?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q5.7	<u>Menyelesaikan</u> semua tugas yang harus dikerjakan?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q5.8	Menyelesaikan tugas-tugas Anda <u>secepat</u> <u>mungkin</u> ?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak dapat melakukan
BERP	ARTISIPASI DI MASYARAKAT. Dalam 30 h	ari terakhir:				
Q 6.1	Seberapa sulit anda <u>bergabung di</u> <u>kegiatan-kegiatan sosial</u> (misalnya, kegiatan budaya, keagamaan, dan lain- lain) seperti orang lain?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q6.2	Seberapa berat masalah yang anda hadapi yang disebabkan oleh <u>hambatan-</u> <u>hambatan</u> di lingkungan sekitar anda?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q6.3	Seberapa sulit anda <u>hidup yang</u> <u>bermartabat</u> karena sikap dan perilaku orang lain?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q6.4	Berapa banyak <u>waktu</u> yang <u>anda</u> habiskan untuk kondisi kesehatan atau hal-hal yang berkaitan dengan kondisi kesehatan anda?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q6.5	Seberapa besar <u>dampak emosional</u> yang <u>anda</u> rasakan dari masalah kesehatan anda?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q6.6	Seberapa besar masalah kesehatan anda <u>menguras kondisi keuangan</u> anda dan keluarga?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa

Q6.7	Seberapa besar masalah yang dihadapi <u>keluarga</u> anda karena masalah kesehatan anda?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
Q6.8	Seberapa sulit anda <u>melakukan sendiri</u> kegiatan-kegiatan untuk <u>bersantai dan</u> <u>bersenang-senang</u> ?	Tidak ada	Ringan	Sedang	Berat	Ekstrim atau tidak bisa
R1	Dalam 30 hari terahir, kira-kira <u>berapa hari</u> masalah-masalah di atas muncul?					i
R2	Selama 30 hari terakhir, berapa hari anda <u>tidak dapat</u> melakukan kegiatan sehari-sehari atau pekerjaan karena masalah kesehatan?				nlah har	i
R3	Selama 30 hari terakhir, dalam berapa harikah anda merasakan				nlah har	·i

Pertanyaan-pertanyaan berikutnya tentang <u>kehidupan anda sehari-hari</u>. Lingkari **satu angka** dari setiap kelompok yang paling sesuai untuk kondisi kesehatan anda pada hari ini..

S1	Kemampuan Berjalan / Bergerak	
	Saya tidak mempunyai kesulitan dalam berjalan / bergerak	1
	Saya mempunyai kesulitan dalam berjalan / bergerak	2
	Saya harus selalu berada di tempat tidur	3
S2	Perawatan Diri	
	Saya tidak mempunyai kesulitan dalam merawat diri sendiri	1
	Saya mempunyai kesulitan untuk mandi atau berpakaian sendiri	2
	Saya tidak bisa mandi atau berpakaian sendiri	3
S 3	Kegiatan yang Biasa Dilakukan (misalnya bekerja, belajar, mengerjakan pekerjaan rumah tangga, kegiatan keluarga, atau bersantai/berekreasi)	
	Saya tidak mempunyai kesulitan dalam mengerjakan kegiatan yang biasa saya lakukan	1
	Saya mempunyai kesulitan dalam mengerjakan kegiatan yang biasa saya lakukan	2
	Saya tidak bisa mengerjakan kegiatan yang biasa saya lakukan	3
S4	Rasa Kesakitan / Tidak Nyaman	
	Saya tidak merasa kesakitan / tidak nyaman	1
	Saya merasa agak kesakitan / tidak nyaman	2
	Saya merasa amat sangat kesakitan / tidak nyaman	3
S5	Rasa Cemas / Murung (Sedih)	
	Saya tidak merasa cemas / murung (sedih)	1
	Saya merasa agak cemas / murung (sedih)	2
	Saya merasa amat sangat cemas / murung (sedih)	3

*** TERIMA KASIH. SEMOGA LEKAS SEMBUH. *** *** MOHON BERIKAN KEPADA PETUGAS PENELITIAN ***

Biarkan dokter/psikolog mengisi halaman-halaman selanjutnya.

Terima kasih.

	1			1
		ID Puskesmas: Nomor U	<u>Jrut</u>	Pasien:
	A - Gejala Somatik			
A1	Apakah anda pernah merasa ngilu, sakit, atau perih dalam	satu bulan terakhir?		1
	ripunan anaa pornan moraoa ngna, bani, aaaa porni aalam	Ya	1	→ A3
		Tidak	2	$\rightarrow A2$
		Thank	-	- 112
A2	Dalam satu bulan terakhir, apakah anda pernah terganggu contohnya sakit kepala atau nyeri lambung?	oleh rasa tidak nyaman,		
	, , , , , , , , , , , , , , , , , , ,	Ya	1	→ A3
		Tidak	2	→ Lanjut ke B
			_	
A3	Apakah rasa sakit atau tidak nyaman ini dikarenakan oleh merasa sedih, khawatir, atau tertekan?	atau lebih parah karena anda		
		Ya	1	→ A4
		Tidak	2	→ Lanjut ke B
A4	Dalam tujuh hari terakhir termasuk (HARI) minggu lalu, be atau tidak nyaman?	erapa hari anda merasa sakit		
		4 hari atau lebih	1	
		1 sampai 3 hari	2	} → A5
		Tidak ada	3	→ A9
A5	Secara total, apakah rasa sakit atau tidak nyaman berlangs pada satu hari dari tujun hari terakhir?	sung selama lebih dari tiga jam		
		Ya	1	
		Tidak	2	
A6	Dalam satu minggu terakhir apakah rasa sakit atau tidak n	-		
		sangat menjengkelkan	1	
		sedikit menjengkelkan	2	
		tidak menjengkelkan?	3	
A7	Apakah rasa sakit atau tidak nyaman mengganggu anda pa yang menarik dalam satu minggu terakhir?	ida saat melakukan kegiatan		
	Jang menurik dulum sutu miliggu terakim i	Ya	1	
		Tidak	2	
		Tuak	2	
A8	Sudah berapa lama anda merasakan sakit atau tidak nyam	an yang harusan anda jelaskan?	<u> </u>	1
no		Kurang dari 2 minggu	1	
		2 minggu, kurang dari 6 bulan	2	
		6 bulan, kurang dari 1 tahun	3	
		1 tahun, kurang dari 2 tahun	4	
		2 tahun atau lebih		
			5	
40	Ceklis klinisi:			1
A9		A (A 7)		
	Jumlahkan kode berwarna abu-abu yang dilingkari (A4, A5	-	0	
		Jika tidak ada yang dilingkari Atau	0	1
		Tuliskan jumlah		→ Lanjut ke B

B - Lelah

B1	Apakah anda memperhatikan bahwa anda sering merasa lelah dalam satu bulan ter	akhir?		
	Ya		1	→ B3
	Tidak		2	→ B2
B2	Dalam satu bulan terakhir, apakan anda pernah merasa kurang energi?	-		
02	Ya		1	→ B3
	Tidak		2	→ Lanjut ke C
	i luax		2	- Lanjut Ke C
B3	Apakah anda mengetahui alasan anda merasa lelah atau kurang energi?	F		
	Үа		1	→ (a)
	Tidak		2	→ B4
	(a) Apakah sebab utamanya? Dapatkah ande memilih dari kartu ini?	F		
	Masalah dengan tidur		1	
	Obat		2	
	Penyakit		3	} → B4
	Bekerja terlalu keras		3 4] , 94
			4 5	
	Khawatir atau alasan psi			. I amint ha C
	Olah raga		6	\rightarrow Lanjut ke C
	Lainnya		7	→ B 4
B4	Dalam tujuh hari terakhir termasuk (HARI) minggu lalu, berapa hari anda merasa le atau kurang energi?	elah		
	4 hari atau lebih		1	
	1 sampai 3 hari		2	} → B5
	Tidak ada		3	→ B10
B5	Secara total, apakah rasa lelah atau kurang energi berlangsung selama lebih dari tig pada satu hari dari tujun hari terakhir?	;a jam		
	Ya		1	
	Tidak		2	
B6	Apakah anda pernah merasa lelah atau kurang energi sehingga harus memaksa diri mengerjakan sesuatu?	anda		
	Ya, sedikitnya satu kali		1	
	Tidak		2	
B7	Apakah anda pernah merasa lelah atau kurang energi pada saat melakukan kegiata anda sukai dalam satu minggu terakhir?	n yang		
	Ya, sedikitnya satu kali		1	→ B9
	Tidak		2	
	Tidak menikmati apapur		3	} → B8
	i idak memkinati apaput		5	
B8	Dalam satu minggu terakhir apakah anda pernah merasa lelah atau kurang energi p saat melakukan kegiatan yang anda pernah sukai?	ada		
	Ya		1	
	Tidak		2	
B9	Sudah berapa lama anda merasa lelah atau kurang energi seperti yang anda jelaska	n?		
	Kurang dari 2 minggu		1	
	2 minggu, kurang dari 6		2	
	6 bulan, kurang dari 1 ta		3	
	1 tahun, kurang dari 2 ta		4	
			•	

		2 tahun atau lebih	5	
B10	Ceklis klinisi:			
DIU	Jumlahkan kode berwarna abu-abu yang dilingkari (B4, B5	5, B6, B7, B8)		
		Jika tidak ada yang dilingkari	0	
		Atau Tulishan iumlah		
		Tuliskan jumlah		→ Lanjut ke C
	C - Konsentrasi dan masalah ingatan			
C1	Dalam satu bulan terakhir, apakah anda pernah mempunya dalam kegiatan anda?	ai masalah berkonsentrasi		
		Ya, punya masalah	1	
		Tidak	2	
C2	Apakah anda memperhatikan bahwa anda sering lupa atau ingatan dalam satu bulan terakhir?	ı mempunyai masalah dengan		
		Ya	1	
		Tidak	2	
62	Kode kilisi			
C3		Pasien bermasalah C1 atau C2	1	→ C4
		Lainnya	2	→ Lanjut ke D
C4	Sejak (HARI) minggu lalu, berapa hari anda mengalami ma	-		
		4 hari atau lebih	1	} → C5
		1 sampai 3 hari Tidak ada	2	→ C9
		Huak aua	3	→ C9
C5	Pasien dengan masalah konsentrasi			
		jangan dijawab apabila C1 = 2	1	→ C7
	Dalam satu minggu terakhir, apakah anda dapat berkonser membaca koran, atau berbicara dengan orang lain tanpa pi			
		Ya	2	
		Tidak / Tidak selalu	1	
C6	Dalam satu minggu terakhir, apakah anda masalah konsen mengerjakan kegiatan yang anda kerjakan atau ingin kerja			
		Ya	1	
		Tidak	2	
C7	Pasien dengan masalah ingatan			
		jangan dijawab apabila C2 = 2	1	→ C8
	Apakah anda pernah lupa satu hal penting dalam tujuh har		1	
		Ya Tidak	1 2	
C8	Sudah berapa lama anda mempunyai masalah konsentrasi		_	
	jelaskan?			
		Kurang dari 2 minggu	1	
		2 minggu, kurang dari 6 bulan	2	
		6 bulan, kurang dari 1 tahun	3	
		1 tahun, kurang dari 2 tahun	4	

		2 tahun atau lebih	5	
C9	Ceklis klinisi: Jumlahkan kode berwarna abu-abu yang dilingkari (C4, C	5, C6, C7) Jika tidak ada yang dilingkari Atau Tuliskan jumlah	0	→ Lanjut ke D
	D - Masalah tidur			
D1	Dalam satu bulan terakhir, apakah anda mempunyai masa masalah dengan kembali tidur apabila anda bangun?	ılah mencoba tertidur atau		
	masalan dengan kemban ndur apabha anda bangun.	Ya Tidak	1 2	\rightarrow D3 \rightarrow D2
D2	Apakah anda tidur lebih dari biasanya dalam satu bulan te			
		Ya Tidak	1 2	→ D3 → Lanjut ke E
D3	Berapa malam dari tujuh malam terakhir anda mempunya	ai masalah tidur? 4 malam atau lebih 1 sampai 3 malam Tidak ada	1 2 3	}→ D4 → D11
D4	Apakah anda mengetahui alasan anda mempunyai masala			
		Ya Tidak	1 2	→ (a) → D5
	(a) Apakah sebab utamanya? Dapatkah ande memilih dari			
		Berisik Shift kerja	12	
		Penyakit	3	
		Khawatir atau pikiran Mengerjakan sesuatu (bayi)	5 6	
		Lelah	7	
		Obat	8	
		Lainnya	9	
D5	Pasien dengan masalah kembali tidur			
	-	jangan dijawab apabila C1 = 2	1	→ D8
	Mengingat satu malam dalam tujuh hari terakhir dimana a lama anda mencoba untuk tertidur?	anda tidur paling sedikit, berapa		
		Paling sedikit 1/4 jam	3	→ D11
		1/4 jam tapi kurang dari 1 jam 1 jam tapi kurang dari 3 jam	1 2	} → D7
		3 jam atau lebih	2	→ D6
D6	Dalam satu minggu terakhir, berapa malam anda mencoba	a untuk tertidur selama 3 jam		
	atau lebih?	4 malam atau lebih	1	
		1 sampai 3 malam	2	
		Tidak ada	3	
				J

D7	Apakah anda terbangun lebih dari dua jam sebelum waktu anda bangun kemudian sulit untuk tidur kembali?			
		Ya Tidak	1 2	}→D10
D8	Pasien dengan masalah tidur lebih dari biasanya			
	Mengingat satu malam dalam tujuh hari terakhir dimana a jam lebih lama anda tidur dibanding biasanya?	nda tidur paling lama, berapa		
		Paling sedikit 1/4 jam	3	→ D11
		1/4 jam tapi kurang dari 1 jam	1	}→D10
		1 jam tapi kurang dari 3 jam	2	
		3 jam atau lebih	2	→ D9
D9	Dalam satu minggu terakhir, berapa malam anda tidur terl	alu lama selama 3 jam atau		
		4 malam atau lebih	1	
		1 sampai 3 malam	2	
		Tidak ada	3	
D10	Sudah berapa lama anda mempunyai masalah tidur sepert	i yang anda jelaskan?		
		Kurang dari 2 minggu	1	
		2 minggu, kurang dari 6 bulan	2	
		6 bulan, kurang dari 1 tahun	3	
		1 tahun, kurang dari 2 tahun	4	
		2 tahun atau lebih	5	
D11	Ceklis klinisi:			
	Jumlahkan kode berwarna abu-abu yang dilingkari (D3, D5	5, D6, D8, D9)		
		Jika tidak ada yang dilingkari	0	
		Atau		
		Tuliskan jumlah)→ Lanjut ke E
	E - Tempramen			
E1	Kebanyakan orang bisa lekas marah walaupun tidak ditunj Apakah anda merasa lekas marah dengan orang di sekitar			

	Apakah anda merasa lekas marah dengan orang di sekitar anda dalam satu bulan terakhir? Ya / tidak lebih dari biasanya Tidak	1 2	→ E3 → E2
E2	Dalam satu bulan terakhir apakah anda lekas marah terhadap hal-hal yang sekarang anda anggap kecil?		
	Ya	1	→ E3
	Tidak	2	→ Lanjut ke F
E3	Sejak (HARI) minggu lalu, berapa hari anda merasa lekas marah?		
	4 hari atau lebih	1	} → E4
	1 sampai 3 hari	2	J . 11
	Tidak ada	3	→ E11
E4	Hal-hal seperti apa yang membuat anda merasa lekas marah dalam satu minggu terakhir?		
E5	Secara total, apakah anda merasa lekas marah selama lebih dari satu jam dalam satu hari sepanjang seminggu terakhir?		

		Ya Tidak	1 2	
E6	Dalam satu minggu terakhir, apakah anda pernah merasa berteriak walaupun akhirnya anda tidak berteriak?	marah sehingga anda ingin		
		Ya Tidak	1 2	
E7	Dalam satu minggu terakhir, apakah anda pernah berteng kehilangan kesabaran terhadap seseorang?	kar atau berkelahi atau		
		Ya Tidak	1 2	→ (a) → E10
	(a) Apakah hal ini terjadi lebih dari sekali selama satu min	nggu terakhir?		
		Satu kali Lebih dari satu kali	1 2	→ E8 → E9
E8	Apakah anda merasa kemarahan anda itu layak?			
		Ya, layak Tidak, tidak layak	2 1	}→E10
E9	Apakah anda merasa setiap kali kemarahan anda itu layal	x?		
		Ya, layak Tidak, sedikitnya satu tdk layak	2	}→E10
E10	Sudah berapa lama anda mempunyai masalah kesabaran	seperti yang anda jelaskan?		
		Kurang dari 2 minggu	1	
		2 minggu, kurang dari 6 bulan	2	
		6 bulan, kurang dari 1 tahun 1 tahun kurang dari 2 tahun	3 4	
		1 tahun, kurang dari 2 tahun 2 tahun atau lebih	5	
E11	Ceklis klinisi:			
	Jumlahkan kode berwarna abu-abu yang dilingkari (E3, E	-		
		Jika tidak ada yang dilingkari	0	
		Atau Tuliskan jumlah		→ Lanjut ke F
	F - Khawatir dengan kesehatan			
F1	Kebanyakan orang bisa khawatir terhadap kesehatan tub	uhnya.		

	Dalam satu bulan terakhir, apakah anda pernah merasa khawatir dengan kesehatan anda? Ya, khawatir Tidak, hanya risau	1 2	→ F3 → F2
F2	Pasien tanpa masalah kesehatan		
	(jangan dijawab ada penyakit)	1	→ Lanjut ke G
	Dalam satu bulan terakhir, apakah anda pernah merasa khawatir anda mempunyai masalah kesehatan yang serius?		
	Үа	1	→ F3
	Tidak	2	→ Lanjut ke G
F3	Sejak (HARI) minggu lalu, berapa hari anda merasa khawatir mengenai masalah kesehatan anda?		

	1 sam	pai 3 hari	1 2 3	} → F4 → F8
F4	Berdasarkan pendapat anda mengenai kesehatan anda yang seb terlalu banyak khawatir?	enarnya, apakah anda		
	Ya		1 2	
F5	Dalam satu minggu terakhir apakah rasa khawatir tersebut	-	_	1
	sanga sediki	it menjengkelkan	1 2 3	
F6	Dalam satu minggu terakhir, apakah anda berhasil menghilangka paling tidak satu kali, dengan mengerjakan hal lain?	an rasa khawatir tersebut		
			2 1	
F7	Sudah berapa lama anda merasa khawatir dengan kesehatan and	la?		1
		0 00	1	l
		00 / 0	2	I
		, 0	3	1
			4 5	1
		_	<u> </u>	1
F8	Ceklis klinisi: Jumlahkan kode berwarna abu-abu yang dilingkari (F3, F4, F5, F	6)		1
		-	0	I
	Atau			1
	Tulis	kan jumlah		→ Lanjut ke G
	G - Depresi			
G1	Kebanyakan orang bisa merasa sedih atau murung kadang-kada Apakah anda pernah merasa sedih atau murung dalam satu bula	-		
	Ya		1	I
	Tidak		2	1
G2	Dalam satu bulan terakhir apakah anda dapat menikmati atau te yang biasanya anda anggap menarik?	rtarik mengerjakan hal-hal		
			1	I
	Tidak	, tidak menikmati/tertarik	2	1

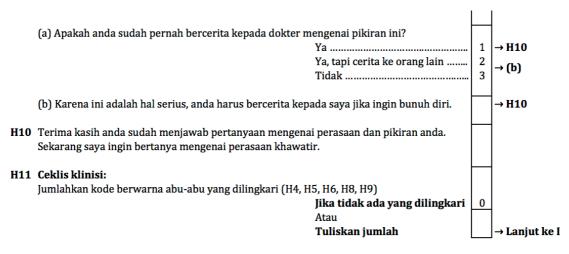
G3	Ко	de	kil	isi
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		2	
G3	Kode kilisi		
	Pasien sedih/murung (G1=1)	1	→ G4
	Pasien sedih/murung (G1=1) Pasien tidak menikmati (G2=2)	2	→ G5
	Lainnya	3	→ Lanjut ke I
G4	Dalam satu minggu terakhir, apakah anda pernah merasa sedih atau murung?		
	Үа	1	$1 \rightarrow C5$
	Tidak	2	J - 7 GS
G5	Pasien yang tidak menikmati atau tertarik kegiatan biasa		
	(jangan dijawab bila G2=1)	1	→ G6

	Dalam satu minggu terakhir, apakah anda dapat menikmati atau tertari	k mengerjakan hal-		
	hal yang biasanya anda anggap menarik?			
	Ya		2	
	Tidak, tidak	menikmati/tertarik	1	
G6	Pasien yang merasa sedih atau murung (G4=1) / tidak menikmati atau	tertarik kegiatan		
	biasa dalam satu minggu terakhir (G5=1)			
	(jangan dijay	wab apabila lainnya)	1	→ G11
	Sejak (HARI) minggu lalu, berapa hari anda merasa sedih atau murung	/ tidak menikmati		
	atau tertarik kegiatan biasa?	L:L	1	
		ebih	1	
		ari	2 3	
	Tuak aua		3	
G7	Apakah anda pernah merasa sedih atau murung / tidak menikmati keg	iatan selama lehih		
u/	dari 3 jam di satu hari dalam seminggu terakhir?	atan selama lebin		
			1	
			2	
			_	
G8	Hal hal seperti apa yang membuat anda merasa demikian? Dapatkah ar	ida memilih?		
	(a) lingkari semua yang cocok Anggota kelu	larga	1	
	Hubungan p	asutri	2	
	Hubungan d	engan teman	3	
	Rumah		4	
	Keuangan		5	
	Kesehatan (d	cth: kehamilan)	6	
		wa	7	
			8	
		um	9	
		tik / berita	10	
			11	
	Tidak diketa	hui	99	
	(h) analyah magalah utamanya?	atu kada dari atas		
	(b) apakah masalah utamanya? isi dengan s	atu kode dari atas		
G9	Dalam seminggu terakhir ketika anda merasa sedih atau murung/tidak	menikmati		
49	kegiatan, apakah anda pernah merasa bahagia ketika satu hal yang bail			
		a satu kali	2	
	•		1	
G10	Sudah berapa lama anda merasa sedih atau murung/tidak menikmati k	egiatan?		
	Kurang dari	2 minggu	1	
	2 minggu, ku	ırang dari 6 bulan	2	
	6 bulan, kura	ang dari 1 tahun	3	
		ang dari 2 tahun	4	
	2 tahun atau	lebih	5	
G11	Ceklis klinisi:			
	Jumlahkan kode berwarna abu-abu yang dilingkari (G5, G6, G7, G9)		-	
		da yang dilingkari	0	
	Atau			
	Tuliskan ju	miah		→ Lanjut ke H

H - Pikiran sedih dan murung

H1	Pasien yang mendapat skor 1 atau lebih di bagian G			
	, , , , , , , , , , , , , , , , , , , ,	jangan jawab bila jumlah G=0	1	→ Lanjut ke I
	Sekarang saya akan bertanya mengenai waktu anda mera			
	menikmati atau tertarik ikut kegiatan. Dalam seminggu te	rakhir apakan perasaan ini lebih		
	parah padi pagi hari atau sore hari, atau sama saja?			
		pagi hari		
		sore hari		
		sama saja / lainnya	3	
H2	Banyak orang yang berperasaan seperti ini mengalami pe	rubahan dalam hubungan		
	pasutri. Dalam satu bulan terakhir, apakah minat anda un			
		meningkat	1	
		berkurang		
		sama saja		
		tidak punya pasangan		
H3	Pada saat anda merasa sedih atau murung / tidak menikm	ati atau tertarik ikut kegiatan		
	yang biasanya menarik untuk anda			
	apakah anda gelisah?	Ya = 1	Td	
	apakah anda menjadi perlahan (cth: jalan lebih perlahan)	Ya = 1	Td	
		Ya = 1	Td	
				1
H4	Dalam seminggu terakhir apakah anda pernah merasa ber	salah atau menyalahkan diri]
	sendiri ketika ada yang salah, walaupun anda tidak menye	-		
		Ya, sedikitnya satu kali	1	
		Tidak	2	
H5	Dalam seminggu terakhir apakah anda pernah merasa and	la tidak sebaik orang lain?]
		Ya	1	
		Tidak	2	
H6	Dalam seminggu terakhir apakah anda pernah merasa put masa depan anda?	cus harapan, contohnya mengenai		
	•	Үа	1	
		Tidak	2	
H7	Kode kilisi			
		Pasien merasa bersalah (H4=1)		
		Pasien tidak sebaik lain (H5=1)	1	→ H8
		Pasien putus harapan (H6=1)		
		Lainnya (H4, H5, H6 = 2)	2	→ H10
H8	Dalam seminggu terakhir apakah anda pernah merasa hid	up anda tidak berarti?		
		Ya	1	→ H9
		Ya, tapi tidak dalam seminggu	2	→ H10
		Tidak	3	
			<u> </u>	
H9	Dalam seminggu terakhir apakah anda pernah berpikir un			
		Ya	1	→ (a)
		Ya, tapi tidak dalam seminggu	2	→ H10
		Tidak	3	



I - Kekhawatiran

I1	Dalam satu bulan terakhir, apakah anda merasa khawatir	lebih dari sewajarnya?		
		Ya, khawatir	1	→ I3
		Tidak, hanya risau	2	→ I2
		•		
I2	Dalam satu bulan terakhir apakah anda pernah merasa kh	nawatir?		
		Ya	1	→ I3
		Tidak	2	→ Lanjut ke J
13	(a) Apakah hal - hal yang anda khawatirkan satu bulan	Anggota keluarga	1	
	terakhir?	Hubungan pasutri	2	
		Hubungan dengan teman	3	
		Rumah	4	
		Keuangan	5	
		Kesehatan (termasuk kehamilan)	_	
		Kesehatan jiwa	7	
		Pekerjaan	8	
		Masalah hukum	9	
		Masalah politik / berita	10	
		Lainnya	11	
		Tidak diketahui	99	
	(b) apakah masalah utamanya?	isi dengan satu kode dari atas		→ I4
I4	Kode kilisi			
	Pasien khawatir mengenai kesehatan	I3(a) = 6	1	→ I5
	Lainnya	Kode lain di I3(a)	2	→ I6
	,			
15	Kode kilisi			
	Pasien hanya khawatir mengenai kesehatan	I3(a) = hanya 6	1	→ Lanjut ke J
	Pasien juga khawatir mengenai hal lain	Kode lain di I3(a)	2	→ (a)
	(a) Untuk beberapa pertanyaan berikutnya, saya ingin an lain, selain mengenai kesehatan	da memikirkan kekhawatiran		
I6	Sejak (HARI) minggu lalu, berapa hari anda merasa khaw	atir dongan hal hal colain		
10	kesehatan anda?	ati uengali liai-liai selalli		

		4 hari atau lebih 1 sampai 3 hari	1 2	}→17
		Tidak ada	3	→ I11
17	Menurut pendapat anda, apakah anda merasa khawatir ya	ng berlebihan?		
		Ya	1	
		Tidak	2	
I8	Dalam satu minggu terakhir apakah rasa khawatir tersebu	ıt		
		sangat menjengkelkan	1	
		sedikit menjengkelkan	2	
		tidak menjengkelkan?	3	
19	Apakah anda pernah merasa khawatir selama lebih dari 3 seminggu terakhir?	jam pada suatu hari dari		
		Ya	1	
		Tidak	2	
I10	Sudah berapa lama anda merasa khawatir mengenai hal-h	al selain kesehatan?		
		Kurang dari 2 minggu	1	
		2 minggu, kurang dari 6 bulan	2	
		6 bulan, kurang dari 1 tahun	3	
		1 tahun, kurang dari 2 tahun	4	
		2 tahun atau lebih	5	
I11	Ceklis klinisi:			
	Jumlahkan kode berwarna abu-abu yang dilingkari (16, 17,	I8, I9)		
		Jika tidak ada yang dilingkari	0	
		Atau		
		Tuliskan jumlah		→ Lanjut ke J
	• • • ·			

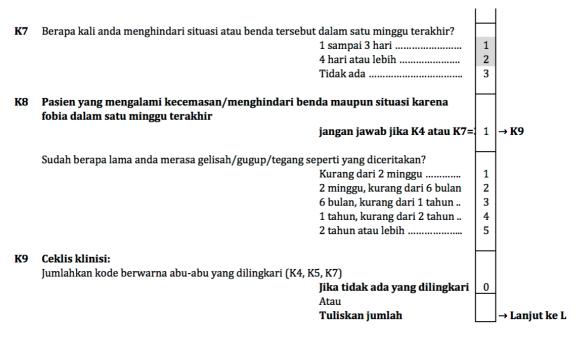
J - Anxietas

J1	Dalam satu bulan terakhir, apakah anda pernah merasa g	elisah atau gugup?		
		Үа	1	→ J3
		Tidak	2	→ J2
J2	Dalam satu bulan terakhir apakah anda pernah merasa ot santai?	ot anda tegang dan tidak bisa		
		Үа	1	
		Tidak	2	
J3	Kadang-kadang orang memiliki fobia, yakni merasa gelisa atau situasi yang sebenarnya tidak berbahaya. Contohnya berbicara di depan orang lain, gelisah ketika jauh dari rur mungkin takut dengan ketinggian. Orang lain merasa gelis	orang mungkin merasa gugup nah atau di ruangan ramai, atau		
	Dalam satu bulan terakhir apakah anda pernah gelisah, gu benda atau situasi yang sebenarnya tidak berbahaya?	ıgup, atau tegang menghadapi		
		Ya	1	
		Tidak	2	
J4	Kode kilisi			
	Pasien melaporkan anxietas dan fobia	J1 = 1 atau J2=1 DAN J3=1	1	→ J5
	Pasien hanya melaporkan anxietas	J1 = 1 atau J2=1	2	→ J7

		Lainnya	3	→ Lanjut ke K
J5	Dalam satu bulan terakhir, jika anda merasa gelisah/gugu takut mengenai situasi tertentu atau anda memang secara		1 2	→ Lanjut ke K → J6
J6	Beberapa pertanyaan berikutnya adalah menyangkut geli spesifik. Saya akan bertanya mengenai kegelisahan oleh k			
	Selama seminggu terakhir, berapa hari anda merasa gelisa	ah/gugup/tegang? 4 hari atau lebih 1 sampai 3 hari Tidak ada	1 2 3	} → J8 → J12
J7	Selama seminggu terakhir, berapa hari anda merasa gelisa	ah/gugup/tegang? 4 hari atau lebih 1 sampai 3 hari Tidak ada	1 2 3	} → J8 → J12
J8	Dalam satu minggu terakhir apakah rasa gelisah/gugup/t	egang tersebut sangat menjengkelkan sedikit menjengkelkan tidak menjengkelkan?	1 2 3	
J9	Dalam satu minggu terakhir jika anda merasa gelisah/gug mengalami gejala-gejala ini?	up/tegang apakah anda Jika ada minimal satu kode ,"Ya" Jika tidak ada, "Tidak"	1 2	
	(a) Lingkari semua gejala yang dialami pasien	Jantung berdebar Tangan bergetar/berkeringat Merasa pusing Sesak nafas Lemas Mulut kering Seakan ingin muntah	1 2 3 4 5 6 7	
J10	Apakah anda pernah merasa gelisah/gugup/tegang selam sedikitnya satu hari dari seminggu terakhir?	a lebih dari 3 jam pada Ya	1	
J11	Sudah berapa lama anda merasa gelisah/gugup/tegang se	Tidak eperti yang diceritakan? Kurang dari 2 minggu 2 minggu, kurang dari 6 bulan 6 bulan, kurang dari 1 tahun 1 tahun, kurang dari 2 tahun 2 tahun atau lebih	2 1 2 3 4 5	
J12	Ceklis klinisi: Jumlahkan kode berwarna abu-abu yang dilingkari (J6, J7,	J8, J9, J10) Jika tidak ada yang dilingkari Atau Tuliskan jumlah	0	→ Lanjut ke K

K - Fobia

K1	Kode kilisi Pasien melaporkan fobia dalam sebulan terakhir J3=1 Lainnya	1 2	→ K3(a) → K2
K2	Kadang-kadang orang menghindari benda atau situasi tertentu karena fobia. Contohnya orang mungkin merasa gelisah di antara keramaian, atau menghindari tempat ramai karena takut merasa gugup atau gelisah.		
	Dalam satu bulan terakhir apakah anda pernah menghindari suatu benda atau situasi karena itu membuat anda gelisah, gugup, atau tegang walau sebenarnya tidak berbahaya? Ya Tidak	1 2	→ K3(b) → Lanjut ke L
К3	(a) Situasi atau benda apa yang membuat anda paling gelisah/gugup/tegang selama satu bulan terakhir? (hanya 1 jawaban) Lingkari kode di (b) kemudian ke K4		
	(b) Situasi atau benda apa yang anda paling hindari selama satu bulan terakhir? (hanya 1)		
	Keramaian/bepergian sendiri Tempat tertutup Situasi sosial, bicara di depan um Melihat darah atau luka Sebab spesifik lainnya	1 2 3 4 5	
	Lainnya (catat)	6	
K4	Pasien yang mengalami kecemasan karena fobia dalam satu bulan terakhir (jangan dijawab jika K1=2)	1	→ K7
	Selama seminggu terakhir, berapa hari anda merasa gelisah/gugup/tegang? 4 hari atau lebih 1 sampai 3 hari Tidak ada	1 2 3	} → K5 → K6
K5	Dalam satu minggu terakhir jika anda merasa gelisah/gugup/tegang apakah anda mengalami gejala-gejala ini?		
	Jika ada minimal satu kode ,"Ya" Jika tidak ada, "Tidak"	1 2	→ (a) → K6
	(a) Lingkari semua gejala yang dialami pasien Jantung berdebar	1	
	Tangan bergetar/berkeringat Merasa pusing Sesak nafas Lemas Mulut kering Seakan ingin muntah	2 3 4 5 6 7	
K6	Merasa pusing Sesak nafas Lemas Mulut kering	3 4 5 6	



L - Panik

L1	Pasien yang mengalami kecemasan dalam satu bulan terakhir		
	(jangan dijawab jika J4=3)	1	→ Lanjut ke M
	Dalam satu bulan terakhir apakah kecemasan anda pernah sebegitu parah sehingga anda panik, misalnya membuat anda merasa akan pingsan jika tidak melakukan sesuatu? Ya	1	→ L2
	Tidak	2	→ Lanjut ke M
L2	Berapa kali hal ini terjadi dalam satu minggu terakhir?		
	Sekali Lebih dari sekali	1 2	}→ L3
	Tidak pernah	3	→ L8
L3	Dalam satu minggu terakhir apakah rasa panik tersebut sedikit mengganggu sangat menjengkelkan	2 1	
L4	Apakah rasa panik yang paling parah berlanjut selama 10 menit atau lebih?		
	Ya Tidak	1 2	
L5	Apakah anda merasa biasa saja (tidak gelisah) di antara perasaan panik?		
	Ya Tidak	1 2	
L6	Pasien yang mengalami kecemasan karena fobia		
	(jangan dijawab jika K1=2)	1	→ L7
	Mengingat benda atau situasi yang anda hindari, apakah panik ini adalah akibat dari benda atau situasi tersebut?		

	Ya Tidak	1 2	
L7	Sudah berapa lama anda mengalami perasaan panik seperti yang diceritakan?		
	Kurang dari 2 minggu	1	
	2 minggu, kurang dari 6 bulan	2	
	6 bulan, kurang dari 1 tahun	3	
	1 tahun, kurang dari 2 tahun	4	
	2 tahun atau lebih	5	
L8	Ceklis klinisi:		
	Jumlahkan kode berwarna abu-abu yang dilingkari (L2, L3, L4)		
	Jika tidak ada yang dilingkari	0	
	Atau		
	Tuliskan jumlah		→ Lanjut ke M
	M - Kompulsi		
M1	Dalam satu bulan terakhir apakah anda memperhatikan bahwa anda mengerjakan sesuatu berulang - ulang kali walaupun anda sudah mengerjakannya, contohnya, bolak-balik melihat apakah anda sudah mengunci mobil atau bolak-balik mencuci tangan?		
	Үа	1	→ M2
	Tidak	2	→ Lanjut ke N
M2	Selama seminggu terakhir, berapa hari anda mengerjakan sesuatu berulang-ulang kali?		
	4 hari atau lebih	1	} → M3
	1 sampai 3 hari	2	j
	Tidak ada	3	→ M9
M3	Sejak (HARI) minggu lalu, hal - hal apa yang anda kerjakan berulang-ulang kali?		
	(catat semua)		
M4	Dalam satu minggu terakhir, apakah anda mencoba berhenti mengulang-ulang (PERILAKU) ini?		
	Үа	1	
	Tidak	2	
ME			
M5	Apakah mengulang-ulang (PERILAKU) ini membuat anda kesal dengan diri anda sendiri?	4	
	Ya, kesal Tidek some sekeli	1 2	
	Tidak sama sekali	2	
M6	Jika ada lebih dari satu hal yang dikerjakan berulang-ulang di M3		
	jangan jawab jika hanya satu	1	→ M7
	,	-	
	Mengingat seminggu terakhir, apa yang lebih sering anda kerjakan berulang-ulang?		
	(pilih satu dari M3)		→ M7
M7	Sejak (HARI) minggu lalu, berapa kali anda mengulang hal yang anda sudah kerjakan? 3 kali atau lebih 2 kali	1	
	2 kali 1 kali	2 3	

M8	Sudah berapa lama anda mengulang-ulang hal yang anda barusan ceritakan?	Г		
	Kurang dari 2 ming	ou -	1	
	2 minggu, kurang da	0	2	
	6 bulan, kurang dar		3	
	1 tahun, kurang dar		4	
	2 tahun atau lebih		5	
			٦	
M9	Ceklis klinisi:			
	Jumlahkan kode berwarna abu-abu yang dilingkari (M2, M4, M5, M7)			
	Jika tidak ada yan	g dilingkari 🕴	0	
	Atau	,	-	
	Tuliskan jumlah			→ Lanjut ke N
	, a company and a company a			,
	N - Obsesi			
N1	Dalam satu bulan terakhir apakah anda mempunyai pikiran buruk atau ide yai	ng muncul		
	berkali-kali, yang anda anggap tidak menyenangkan dan tidak ingin anda pikir			
	tetap muncul di pikiran anda?			
	Ya		1	→ N2
	Tidak		2	→ Lanjut ke O
N2	Boleh saya tahu, apakah ini pikiran atau ide yang sama yang muncul berkali-ka	ali atau anda		
	hanya khawatir mengenai satu hal misalnya kesehatan?			
	Sama		1	→ N3
	Hanya khawatir	7	2	→ Lanjut ke O
N3	Apakah pikiran buruk atau ide tidak menyenangkan yang terus menerus meng	gganggu		
	pikiran anda?			
	(jangan d	iberi contoh)		
NA	Criels (IIADI) win zwy leby, herene here en de wermennen i sileinen etwy ide terrel		_	
N4	Sejak (HARI) minggu lalu, berapa hari anda mempunyai pikiran atau ide tersel 4 hari atau lebih		1	
	1 sampai 3 hari		1 2	} → N5
	Tidak ada		23	→ N9
			3	-> IN 5
N5	Dalam satu minggu terakhir, apakah anda mencoba menghentikan pikiran ata tersebut?	u ide		
	Ya		1	
	Tidak		2	
N6	Apakah pikiran atau ide tersebut membuat anda kesal dengan diri anda sendir	ri?		
	Ya, kesal	1	1	
	Tidak sama sekali	2	2	
		L		
N7	Dalam seminggu terakhir, berapa lama ide tersebut bertahan setiap muncul?			
	15 menit atau lebih		1	
	kurang dari 15 men	it 2	2	
NO	Cudah harana lama anda mananan atlainan atau tila anan anda haran it	lran2	\neg	
N8	Sudah berapa lama anda mempunya pikiran atau ide yang anda barusan cerita		1	
	Kurang dari 2 ming	-	1	
	2 minggu, kurang da		2	
	6 bulan, kurang dar 1 tahun, kurang dar		3 4	
	2 tahun atau lebih		4 5	
	2 tanuli atau lebin		J	

N9	Ceklis klinisi: Jumlahkan kode berwarna abu-abu yang dilingkari (N4, N5, N6, N7) Jika tidak ada yang dilingkari Atau Tuliskan jumlah	0	→ Lanjut ke O
	0 - Efek keseluruhan		
	Pasien yang mempunya skor 2 atau lebih di salah satu bagian (A hingga N) (jangan dijawab jika skor 0 -1)	1	→ Cek Akhir
	Sekarang saya ingin bertanya mengenai bagaimana hal-hal yang barusan anda ceritakan mempengaruhi hidup anda secara keseluruhan.		
	Dalam seminggu terakhir, apakah hal-hal yang anda ceritakan dan perasaan anda pernah menghentikan anda dari melakukan hal-hal yang anda sebetulnya ingin kerjakan? Ya Tidak	1 2	→ (a) → (b)
	(a) Dalam satu minggu terakhir, apakah hal-hal tersebut menghentikan anda sekali atau lebih dari sekali? Sekali Lebih dari sekali	1 2	}→ Cek Akhir
	(b) Apakah hal-hal tersebut membuat kegiatan anda lebih sulit walaupun anda bisa menyelesaikan semua kegiatan anda? Ya Tidak	1 2	}→ Cek Akhir

CCK AKIIII

A - Gejala Somatik	A9 =
B - Lelah	B10 =
C - Konsentrasi dan Masalah Ingatan	C9 =
D - Masalah Tidur	D11 =
E - Tempramen	E11 =
F - Khawatir dengan Kesehatan	F8 =
G - Depresi	G11 =
H - Pikiran Sedih dan Murung	H11 =
I - Kekhawatiran	I11 =
J - Anxietas	J12 =
K - Fobia	K9 =
L - Panik	L8 =
M - Kompulsi	M9 =
N - Obsesi	N9 =

HoNOS

_								
	unjuk : Setiap pertanyaan dinilai berdasarkan 5 tingkat keseriusan (0-	4) se	ebag	ai be	riku	t:		
	dak ada masalah.							
	asalah kecil tanpa penanggulangan berarti.							
	asalah menengah. asalah dengan keseriusan sementara.							
	asalah serius sampai sangat serius.							
	lak diketahui atau tidak sesuai (tidak dapat diterapkan pada pasien).							
No	Masalah							
1	Hiperaktif, agresif, disruptif, atau gaduh gelisah	0	1	2	3	4	?	
2	Perlukaan diri sendiri non-kecelakaan	0	1	2	3	4	?	
3	Masalah dengan minuman atau obat-obatan	0	1	2	3	4	?	
4	Masalah kognitif	0 1 2 3 4 ?				?		
5	Penyakit fisik atau masalah disabilitas (ketidak mampuan)	0 1 2 3 4 ?						
6	Masalah terkait halusinasi dan waham				3	4	?	
7	Masalah dengan mood yang depresif		1	2	3	4	?	
8	Masalah mental dan perilaku lain		1	2	3	4	?	
0	(perinci gangguan A, B, C, D, E, F, G, H, I, atau J)	Rincian:						
9	Masalah dengan hubungan	0 1 2 3 4			?			
10	Masalah dengan aktivitas sehari-hari	0	1	2	3	4	?	
11	Masalah dengan kondisi tempat tinggal sehari-hari	0	1	2	3	4	?	
12	Masalah dengan pekerjaan dan aktivitas			2	3	4	?	
	TOTAL							
A Fol B Kee C Ma D Re E Ma F Sor	i <mark>k butir pertanyaan no. 8</mark> bia – termasuk ketakutan meninggalkan rumah, kerumunan, tempat publik, bepergia cemasan dan panik salah obsesi dan kompulsi aksi terhadap hal-hal yang memancing stres dan trauma salah disosiatif (konversi) matisasi – bersikukuh memiliki komplain fisik meskipun penyelidikan menyelurul but tidak ada					-		

G Masalah dengan nafsu makan, baik yang berlebih maupun tidak ada sama sekali H Gangguan tidur I Masalah seksual J Masalah yang tidak terdefinisi termasuk mood ekspansif

Diagnosa Gangguan Jiwa:

Tanggal Pengisian:	

Tanggal Follow-up 6 Bulan:	
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Nomor HP Pasien:	
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In English: WHODAS 2.0, EQ-5D-3L, and CIS-R

Patient Name:

WHODAS 2.0

World Health Organization Disability Assessment Schedule 2.0 36-item version, self-administered

Age: _____ Sex: D Male D Female

Date:

This questionnaire asks about <u>difficulties due to health/mental health conditions</u>. Health conditions include **diseases or illnesses**, **other health problems that may be short or long lasting**, **injuries**, **mental or emotional problems**, **and problems with alcohol or drugs**. Think back over the <u>past 30 days</u> and answer these questions thinking about how much difficulty you had doing the following activities. For each question, please circle only <u>one</u> response.

							Clinician Use O		Only
	Numeric scores assigned to each of the items:	1	2	3	4	5	E	. <u> </u>	e i a
In the la	ast 30 days, how much difficulty did you have in:						Raw Item Score	Raw Domain Score	Average Domain Score
Understanding and communicating						Rav	- 9 %	s Dc	
D1.1	<u>Concentrating</u> on doing something for <u>ten</u> minutes?	None	Mild	Moderate	Severe	Extreme or cannot do			
D1.2	Remembering to do important things?	None	Mild	Moderate	Severe	Extreme or cannot do			
D1.3	Analyzing and finding solutions to problems in day-to-day life?	None	Mild	Moderate	Severe	Extreme or cannot do			
D1.4	Learning a <u>new task</u> , for example, learning how to get to a new place?	None	Mild	Moderate	Severe	Extreme or cannot do		30	5
D1.5	Generally understanding what people say?	None	Mild	Moderate	Severe	Extreme or cannot do			
D1.6	Starting and maintaining a conversation?	None	Mild	Moderate	Severe	Extreme or cannot do			
Gettin	g around								1
D2.1	Standing for long periods, such as 30 minutes?	None	Mild	Moderate	Severe	Extreme or cannot do			
D2.2	Standing up from sitting down?	None	Mild	Moderate	Severe	Extreme or cannot do		-	
D2.3	Moving around inside your home?	None	Mild	Moderate	Severe	Extreme or cannot do		25	5
D2.4	<u>Getting out</u> of your <u>home</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do			
D2.5	<u>Walking a long distance</u> , such as a kilometer (or equivalent)?	None	Mild	Moderate	Severe	Extreme or cannot do			
Self-ca	ire								
D3.1	Washing your whole body?	None	Mild	Moderate	Severe	Extreme or cannot do			
D3.2	Getting <u>dressed</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do			
D3.3	Eating?	None	Mild	Moderate	Severe	Extreme or cannot do		20	5
D3.4	Staying by yourself for a few days?	None	Mild	Moderate	Severe	Extreme or cannot do			
Gettin	g along with people								
D4.1	Dealing with people you do not know?	None	Mild	Moderate	Severe	Extreme or cannot do			
D4.2	Maintaining a friendship?	None	Mild	Moderate	Severe	Extreme or cannot do			
D4.3	Getting along with people who are <u>close</u> to you?	None	Mild	Moderate	Severe	Extreme or cannot do		25	5
D4.4	Making new friends?	None	Mild	Moderate	Severe	Extreme or cannot do			
D4.5	Sexual activities?	None	Mild	Moderate	Severe	Extreme or cannot do			

							Clini	cian Use	Only
	Numeric scores assigned to each of the items:	1	2	3	4	5	E	۲.	e, c
In the last 30 days, how much difficulty did you have in:							Raw Item Score	Raw Domain Score	/erag
Life activities—Household						Rav	<u> </u>	₹ 0 v	
D5.1	Taking care of your <u>household responsibilities</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do			
D5.2	Doing most important household tasks well?	None	Mild	Moderate	Severe	Extreme or cannot do			
D5.3	Getting all of the household work <u>done</u> that you needed to do?	None	Mild	Moderate	Severe	Extreme or cannot do		20	5
D5.4	Getting your household work done as <u>quickly</u> as needed?	None	Mild	Moderate	Severe	Extreme or cannot do			
Life ac	tivities—School/Work	I.							
	work (paid, non-paid, self-employed) or go to schoo wise, skip to D6.1.	ol, comp	olete que	estions D5.	5–D5.8,	below.			
Becaus	se of your health condition, in the past 30 days, how	w much	difficult	<u>y</u> did you h	ave in:				
D5.5	Your day-to-day <u>work/school</u> ?	None	Mild	Moderate	Severe	Extreme or cannot do			
D5.6	Doing your most important work/school tasks well?	None	Mild	Moderate	Severe	Extreme or cannot do			
D5.7	Getting all of the work <u>done</u> that you need to do?	None	Mild	Moderate	Severe	Extreme or cannot do		20	5
D5.8	Getting your work done as <u>quickly</u> as needed?	None	Mild	Moderate	Severe	Extreme or cannot do			
Partici	ipation in society								
In the	past <u>30 days</u> :	1	-	1		1		1	1
D6.1	How much of a problem did you have in joining in community activities (for example, festivities, religious, or other activities) in the same way as anyone else can?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.2	How much of a problem did you have because of <u>barriers or hindrances</u> around you?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.3	How much of a problem did you have <u>living</u> with dignity because of the attitudes and actions of others?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.4	How much <u>time</u> did <u>you</u> spend on your health condition or its consequences?	None	Some	Moderate	A Lot	Extreme or cannot do		40	5
D6.5	How much have <u>you</u> been <u>emotionally affected</u> by your health condition?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.6	How much has your health been a <u>drain on the</u> <u>financial resources</u> of you or your family?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.7	How much of a problem did your <u>family</u> have because of your health problems?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.8	How much of a problem did you have in doing things by yourself for relaxation or pleasure?	None	Mild	Moderate	Severe	Extreme or cannot do			
D6.8	How much of a problem did you have in doing	None	Mild	Mod			erate Severe cannot do	erate Severe cannot do	erate Severe

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WHODAS 2.0

World Health Organization Disability Assessment Schedule 2.0

36-item version, self-administered

The adult self-administered version of the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) is a 36-item measure that assesses disability in adults age 18 years and older. It assesses disability across six domains, including understanding and communicating, getting around, self-care, getting along with people, life activities (i.e., household, work, and/or school activities), and participation in society. If the adult individual is of impaired capacity and unable to complete the form (e.g., a patient with dementia), a knowledgeable informant may complete the proxy-administered version of the measure, which is available at <u>www.psychiatry.org/dsm5</u>. Each item on the self-administered version of the WHODAS 2.0 asks the individual to rate how much difficulty he or she has had in specific areas of functioning during the past 30 days.

WHODAS 2.0 Scoring Instructions Provided by World Health Organization

WHODAS 2.0 Summary Scores: There are two basic options for computing the summary scores for the WHODAS 2.0 36-item full version.

Simple: The scores assigned to each of the items—"none" (1), "mild" (2), "moderate" (3), "severe" (4), and "extreme" (5)—are summed. This method is referred to as simple scoring because the scores from each of the items are simply added up without recoding or collapsing of response categories; thus, there is no weighting of individual items. This approach is practical to use as a hand-scoring approach, and may be the method of choice in busy clinical settings or in paper-and-pencil interview situations. As a result, the simple sum of the scores of the items across all domains constitutes a statistic that is sufficient to describe the degree of functional limitations.

Complex: The more complex method of scoring is called "item-response-theory" (IRT)–based scoring. It takes into account multiple levels of difficulty for each WHODAS 2.0 item. It takes the coding for each item response as "none," "mild," "moderate," "severe," and "extreme" separately, and then uses a computer to determine the summary score by differentially weighting the items and the levels of severity. The computer program is available from the WHO Web site. The scoring has three steps:

- Step 1—Summing of recoded item scores within each domain.
- Step 2—Summing of all six domain scores.
- Step 3—Converting the summary score into a metric ranging from 0 to 100 (where 0 = no disability; 100 = full disability).

WHODAS 2.0 Domain Scores: WHODAS 2.0 produces domain-specific scores for six different functioning domains: cognition, mobility, self-care, getting along, life activities (household and work/school) and participation.

WHODAS 2.0 Population Norms: For the population norms for IRT-based scoring of the WHODAS 2.0 and for the population distribution of IRT-based scores for WHODAS 2.0, please see http://www.who.int/classifications/icf/Pop norms distrib IRT scores.pdf

Additional Scoring and Interpretation Guidance for DSM-5 Users

The clinician is asked to review the individual's response on each item on the measure during the clinical interview and to indicate the self-reported score for each item in the section provided for "Clinician Use Only." However, if the clinician determines that the score on an item should be different based on the clinical interview and other information available, he or she may indicate a corrected score in the raw item score box. Based on findings from the DSM-5 Field Trials in adult patient samples across six sites in the United States and one in Canada, DSM-5 recommends calculation and use of average scores for each domain and for general disability. The **average scores** are comparable to the WHODAS 5-point scale, which allows the clinician to think of the individual's disability in terms of none (1), mild (2), moderate (3), severe (4), or extreme (5). The average domain and general disability scores were found to be reliable, easy to use, and clinically useful to the clinicians in the DSM-5 Field Trials. The **average domain score** is calculated by dividing the raw domain score by the number of items in the domain (e.g., if all the items within the "understanding and communicating" domain are rated as being moderate then the average domain score would be 18/6 = 3, indicating moderate disability). The **average general disability score** is calculated by dividing the raw overall score by number of items in the measure (i.e., 36). The individual should be encouraged to complete all of the items on the WHODAS 2.0. If no response is given on 10 or more items of the measure (i.e., more than 25% of the 36 total items), calculation of the simple and average general disability scores may not be helpful. If 10 or more of the total items on the measure are missing but the items for some of the domains are 75%–100% complete, the simple or average domain scores may be used for those domains.

Frequency of Use

To track change in the individual's level of disability over time, the measure may be completed at regular intervals as clinically indicated, depending on the stability of the individual's symptoms and treatment status. Consistently high scores on a particular domain may indicate significant and problematic areas for the individual that might warrant further assessment and intervention.



Health of the Nation Outcome Scales (HoNOS)

HoNOS rating guidelines

- Rate items in order from 1 to 12.
- Use all available information in making your rating.
- Do not include information already rated in an earlier item.
- Consider both the degree of distress the problem causes and the effect it has on behaviour
- Rate the most severe problem that occurred in the period rated.
- The rating period is generally the preceding two weeks, except at discharge from inpatient care, when it is the previous three days.
- Each item is rated on a five-point item of severity (0 to 4) as follows:
 - 0 No problem.
 - **1** Minor problem requiring no formal action.
 - 2 Mild problem.
 - 3 Problem of moderate severity.
 - 4 Severe to very severe problem.
 - 9 Not known or not applicable.
- As far as possible, the use of rating point 9 should be avoided, because missing data make scores less comparable over time or between settings.
- Specific information on how to rate each point on each item is provided in the Glossary.

Eagar, K. Buckingham, B. Coombs, T. Trauer T, Graham, C. Eagar, L. and Callay, T (2000) Victorian outcome measurement strategy resource manual. Victorian Department of Human Services.



1

Overactive, aggressive, disruptive or agitated behaviour

<u>Include</u> such behaviour due to any cause, eg, drugs, alcohol, dementia, psychosis, depression, etc.

Do <u>not</u> include bizarre behaviour, rated at Scale 6.

- 0 No problems of this kind during the period rated.
- 1 Irritability, quarrels, restlessness etc. Not requiring action.
- 2 Includes aggressive gestures, pushing or pestering others; threats or verbal aggression; lesser damage to property (eg, broken cup or window); marked overactivity or agitation.
- 3 Physically aggressive to others or animals (short of rating 4); threatening manner; more serious over-activity or destruction of property.
- 4 At least one serious physical attack on others or on animals; destruction of property (e.g., fire-setting); serious intimidation or obscene behaviour.

2 Non-accidental self-injury

Do <u>not</u> include <u>accidental</u> self-injury (due eg, to dementia or severe learning disability); the cognitive problem is rated at Scale 4 and the injury at Scale 5.

Do <u>not</u> include illness or injury as a direct consequence of drug or alcohol use rated at Scale 3, (e.g. cirrhosis of the liver or injury resulting from drunk driving are rated at Scale 5).

- 0 No problem of this kind during the period rated.
- 1 Fleeting thoughts about ending it all, but little risk during the period rated; no selfharm.
- 2 Mild risk during period; includes non-hazardous self-harm eg, wrist-scratching.
- 3 Moderate to serious risk of deliberate self-harm during the period rated; includes preparatory acts eg, collecting tablets.
- 4 Serious suicidal attempt or serious deliberate self-injury during the period rated.





3 Problem drinking or drug-taking

Do <u>not</u> include aggressive or destructive behaviour due to alcohol or drug use, rated at Scale 1.

- Do <u>not</u> include physical illness or disability due to alcohol or drug use, rated at Scale 5.
- 0 No problem of this kind during the period rated.
- 1 Some over-indulgence, but within social norm.
- 2 Loss of control of drinking or drug-taking; but not seriously addicted.
- 3 Marked craving or dependence on alcohol or drugs with frequent loss of control, risk taking under the influence, etc.
- 4 Incapacitated by alcohol or drug problems.

4 Cognitive problems

<u>Include</u> problems of memory, orientation and understanding associated with any disorder: learning disability, dementia, schizophrenia, etc.

Do <u>not</u> include temporary problems (e.g. hangovers) resulting from drug or alcohol use, rated at Scale 3.

- 0 No problem of this kind during the period rated.
- 1 Minor problems with memory or understanding e.g. forgets names occasionally.
- 2 Mild but definite problems, e.g. has lost way in a familiar place or failed to recognise a familiar person; sometimes mixed up about simple decisions.
- 3 Marked disorientation in time, place or person, bewildered by everyday events; speech is sometimes incoherent, mental slowing.
- 4 Severe disorientation, e.g. unable to recognise relatives, at risk of accidents, speech incomprehensible, clouding or stupor.

3



5 Physical illness or disability problems

<u>Include</u> illness or disability from any cause that limits or prevents movement, or impairs sight or hearing, or otherwise interferes with personal functioning.

<u>Include</u> side-effects from medication; effects of drug/alcohol use; physical disabilities resulting from accidents or self-harm associated with cognitive problems, drunk driving etc.

Do not include mental or behavioural problems rated at Scale 4.

- 0 No physical health problem during the period rated.
- 1 Minor health problem during the period (eg, cold, non-serious fall, etc).
- 2 Physical health problem imposes mild restriction on mobility and activity.
- 3 Moderate degree of restriction on activity due to physical health problem.
- 4 Severe or complete incapacity due to physical health problem.

6 Problems associated with hallucinations and delusions

Include hallucinations and delusions irrespective of diagnosis.

Include odd and bizarre behaviour associated with hallucinations or delusions.

Do <u>not</u> include aggressive, destructive or overactive behaviours attributed to hallucinations or delusions, rated at Scale 1.

- 0 No evidence of hallucinations or delusions during the period rated.
- 1 Somewhat odd or eccentric beliefs not in keeping with cultural norms.
- 2 Delusions or hallucinations (eg, voices, visions) are present, but there is little distress to patient or manifestation in bizarre behaviour, that is, moderately severe clinical problem.
- 3 Marked preoccupation with delusions or hallucinations, causing much distress and/or manifested in obviously bizarre behaviour, that is, moderately severe clinical problem.
- 4 Mental state and behaviour is seriously and adversely affected by delusions or hallucinations, with severe impact on patient.





Problems with depressed mood

7

Do <u>not</u> include over-activity or agitation, rated at Scale 1.

Do <u>not</u> include suicidal ideation or attempts, rated at Scale 2.

Do <u>not</u> include delusions or hallucinations, rated at Scale 6.

- 0 No problems associated with depressed mood during the period rated.
- 1 Gloomy; or minor changes in mood.
- 2 Mild but definite depression and distress: eg, feelings of guilt; loss of self-esteem.
- 3 Depression with inappropriate self-blame, preoccupied with feelings of guilt.
- 4 Severe or very severe depression, with guilt or self-accusation.

8 Other mental and behavioural problems

<u>Rate</u> only the most severe clinical problem <u>not</u> considered at items 6 and 7 as follows: specify the type of problem by entering the appropriate letter: **A** phobic: **B** anxiety; **C** obsessive-compulsive; **D** stress; **E** dissociative; **F** somatoform; **G** eating; **H** sleep; **I** sexual; **J** other, specify.

- 0 No evidence of any of these problems during period rated.
- 1 Minor non-clinical problems.
- 2 A problem is clinically present at a mild level, eg, patient/client has a degree of control.
- 3 Occasional severe attack or distress, with loss of control eg, has to avoid anxiety provoking situations altogether, call in a neighbour to help, etc., that is, a moderately severe level of problem.

5

4 Severe problem dominates most activities.



9 Problems with relationships

<u>Rate</u> the patient's most severe problem associated with active or passive withdrawal from social relationships, and/or non-supportive, destructive or self-damaging relationships.

- 0 No significant problems during the period.
- 1 Minor non-clinical problems.
- 2 Definite problems in making or sustaining supportive relationships: patient complains and/or problems are evident to others.
- 3 Persisting major problems due to active or passive withdrawal from social relationships, and/or to relationships that provide little or no comfort or support.
- 4 Severe and distressing social isolation due to inability to communicate socially and/or withdrawal from social relationships.

10 Problems with activities of daily living

<u>Rate</u> the overall level of functioning in activities of daily living (ADL): eg, problems with <u>basic activities of self-care</u> such as eating, washing, dressing, toilet; also <u>complex skills</u> such as budgeting, organising where to live, occupation and recreation, mobility and use of transport, shopping, self-development, etc.

<u>Include</u> any lack of motivation for using self-help opportunities, since this contributes to a lower overall level of functioning.

Do <u>not</u> include lack of opportunities for exercising intact abilities and skills, rated at Scale 11 and Scale 12.

- 0 No problems during period rated; good ability to function in all areas.
- 1 Minor problems only eg, untidy, disorganised.
- 2 Self-care adequate, but major lack of performance of one or more complex skills (see above).
- 3 Major problems in one or more areas of self-care (eating, washing, dressing, toilet) as well as major inability to perform several complex skills.
- 4 Severe disability or incapacity in all or nearly all areas of self-care and complex skills.



11 Problems with living conditions

<u>Rate</u> the overall severity of problems with the quality of living conditions and daily domestic routine.

Are the <u>basic necessities</u> met (heat, light, hygiene)? If so, is there help to cope with disabilities and a <u>choice of opportunities to use skills and develop new ones</u>?

Do not rate the level of functional disability itself, rated at Scale 10.

NB: Rate patient's <u>usual</u> accommodation. If in acute ward, rate the home accommodation. If information not obtainable, rate 9.

- 0 Accommodation and living conditions are acceptable; helpful in keeping any disability rated at Scale 10 to the lowest level possible, and supportive of self-help.
- 1 Accommodation is reasonably acceptable although there are minor or transient problems (eg, not ideal location, not preferred option, doesn't like food, etc).
- 2 Significant problems with one or more aspects of the accommodation and/or regime (eg, restricted choice; staff or household have little understanding of how to limit disability, or how to help develop new or intact skills).
- 3 Distressing multiple problems with accommodation (eg, some basic necessities absent); housing environment has minimal or no facilities to improve patient's independence.
- 4 Accommodation is unacceptable (eg, lack of basic necessities, patient is at risk of eviction, or 'roofless', or living conditions are otherwise intolerable making patient's problems worse).

12 Problems with occupation and activities

<u>Rate</u> the overall level of problems with quality of day-time environment. Is there help to cope with disabilities, <u>and opportunities for maintaining or improving occupational and</u> <u>recreational skills and activities</u>? Consider factors such as stigma, lack of qualified staff, access to supportive facilities, eg, staffing and equipment of day centres, workshops, social clubs, etc.

Do not rate the level of functional disability itself, rated at Scale 10.

NB: Rate the patient's <u>usual</u> situation. If in acute ward, rate activities during period before admission. If information not available, rate 9.

- 0 Patient's day-time environment is acceptable; helpful in keeping any disability rated at Scale 10 to the lowest level possible, and supportive of self-help.
- 1 Minor or temporary problems, eg, late pension cheques, reasonable facilities available but not always at desired times etc.
- 2 Limited choice of activities, eg, there is a lack of reasonable tolerance (eg, unfairly refused entry to public library or baths etc.); or handicapped by lack of a permanent address; or insufficient carer or professional support; or helpful day setting available but for very limited hours.
- 3 Marked deficiency in skilled services available to help minimise level of existing disability; no opportunities to use intact skills or add new ones; unskilled care difficult to access.
- 4 Lack of any opportunity for daytime activities makes patient's problem worse.



* A Somatic symptoms			1
A1 Have you had any sort of ache or pa	in in the past month?		
	Yes	1	→ A3
	No	2	→ A2
A2 During the past month have you bee of discomfort, for example, headach	en troubled by any sort e or indigestion?		
	Yes	1	→ A3
	No	2	→ Go to section B
A3 Was this ache or pain/discomfort br because you were feeling low, anxio	ought on or made worse ous or stressed?		
If informant has more than	Yes	1	→ A4
one pain/discomfort, refer to ANY of them	No	2	→ Go to Section B
A4 In the past seven days, including las many days have you noticed the ach	t (DAY OF WEEK), on how e or pain/discomfort?		
	4 days or more	1	I→A5
	1 to 3 days	2	
	None	3	→ A9
A5 In total, did the ache or pain/discom on any day in the past week/on that			
	Yes	1	
	No	2	

A6	In the past week, has the ac	che or pain/discomfort been		
	р :	very unpleasant	1	
	Running prompt	a little unpleasant	2	
		or not unpleasant?	3	
A7	Has the ache or pain/discor doing something interesting	nfort bothered you when you were g in the past week?		
		Yes	1	
		No/has not done anything interesting	2	
A8	How long have you been for ache or pain/discomfort as			
		less than 2 weeks	1	
[Show card 2	2 weeks but less than 6 months	2	
		6 months but less than 1 year	3	
		1 year but less than 2 years	4	
		2 years or more	5	
A9	Interviewer check:			
	Sum codes which you has shaded boxes at A4, A5,			
		Ring '0' if sum of codes is zero	0	
		or		→Insert score
		enter score		on check card, then go to section B
				_

* B Fatigue				7
B1 Have you noticed that in the past month?	you've been getting tired			
		Yes	1	→ B3
		No	2	\rightarrow B2
B2 During the past month, lacking in energy?	, have you felt you've been			
		Yes	1	→ B3
		No	2	→ Go to section (
B3 Do you know why you	have been feeling tired/lack	king in energy?		1
		Yes	1	→ (a)
		No	2	→ B4
(a) What is the main re	eason? Can you choose from	n this card?		1
	Problems with sleep		1	h
Show card 3	Medication		2	
Code one	Physical illness		3	→ B4
only	Working too hard (inc afte	e. housework, looking er baby)	4	
	Stress, worry or other	psychological reason	5	μ
	Physical exercise		6	→ Go to section
	Other		7	$\rightarrow B4$
B4 In the past seven days, on how many days hav	including last (DAY OF W e you felt tired/lacking in e	EEK) nergy?		
		4 days or more	1	
		1 to 3 days	2	\rightarrow B5
		None	3	→ B10
				-
B5 Have you felt tired/lacl than 3 hours in total on	king in energy for more any day in the past week?			
		Yes	1	

B6	Have you felt so tired/lac you've had to push yourse during the past week?			
		Yes, on at least one occasion	1	
		No	2	
B7	Have you felt tired/lackin things that you enjoy dur			
		Yes, at least once	1	→ B9
		No	2	B8
	Spontaneous	Does not enjoy anything	3	
B8	Have you in the past wee when doing things that yo	k felt tired/lacking in energy u used to enjoy? Yes No	1 2	
B9	How long have you been in the way you have just	feeling tired/lacking in energy lescribed?		
		less than 2 weeks	1	
[Show card 2	2 weeks but less than 6 months	2	
		6 months but less than 1 year	3	
		1 year but less than 2 years	4	
B1() Interviewer check:	2 years or more	5	
	Sum codes which you shaded boxes at B4, B	have ringed in the 5, B6, B7 and B8.		
		Ring '0' if sum of codes is zero	0	
		or		→Insert score on check card,
		enter score		then go to section C

* C Concentration and forgetfulness	r	1
C1 In the past month, have you had any problems in concentrating on what you are doing?		
Yes, problems concentrating	1	
No	2	
C2 Have you noticed any problems with forgetting things in the past month?		
Yes	1	
No	2	
C3 Interviewer code		
Informant has problems concentrating or forgets things (coded 1 at C1 or C2)	1	→C4
Others	2	→ Go to
Oulers	2	section D
 C4 Since last (DAY OF WEEK), on how many days have you noticed problems with your concentration/memory? 4 days or more	1 2 3]→C5 →C9
C5 Informants who had concentration problems		
DNA: others (coded 2 at C1)	1	→C7
In the past week could you concentrate on a TV programme, read a newspaper article or talk to someone without your mind		
wandering? Yes	2	
No/not always	1	
C6 In the past week, have these problems with your concentration actually stopped you from getting on with things you used to do or would like to do?		
Yes	1	
No	2	

C7	Informants who had memory problems		
	DNA: others (coded 2 at C2)	1	→ C8
	(Earlier you said you have been forgetting things.) Have you forgotten anything important in the past seven days?		
	Yes	1	
	No	2	
C8	How long have you been having the problems with your concentration/memory as you have described?		
	Less than 2 weeks	1	
	2 weeks but less than 6 monthss	2	
	Show card 2 6 months but less than1 year	3	
	1 year but less than 2 years	4	
	2 years or more	5	
C9	Interviewer check:		
	Sum codes which you have ringed in the shaded boxes at C4, C5, C6 and C7.		
	Ring '0' if sum of codes is zero	0	Г П
	or		→Insert score
	enter score —————		☐ on check card, ☐ then go to section D

* D Sleep problems D1 In the past month, have you been having problems with trying to get to sleep or with getting back to sleep if you woke up or were woken up? → D3 Yes 1 No 2 → D2 D2 Has sleeping more than you usually do been a problem for you in the past month? Yes →D3 1 No 2 Go to section E D3 On how many of the past seven nights did you have problems with your sleep? 1 4 nights or more •D4 2 1 to 3 nights None 3 +D11 D4 Do you know why you are having problems with your sleep? Yes 1 → (a) No 2 →D5 (a) Can you look at this card and tell me the main reason for these problems? 1 Noise Show card 4 Shift work/too busy to sleep 2 Illness/discomfort 3 Code one only Worry/thinking 4 5 Needing to go to the toilet Having to do something (e.g. look after baby) 6 7 Tired 8 Medication Other 9

D5 Informants who had	problems trying to get (back) to sleep]	
	DNA : others (coded 2 at D1)	1	→ D8	
past week, how long of sleep? (If you woke u	Thinking about the night you had the least sleep in the past week, how long did you spend trying to get to sleep? (If you woke up or were woken up I want you to allow a quarter of an hour to get back to sleep).			
Only include time spent trying to get	Less than 1/4 hr At least 1/4 hr but less than 1 hr	3	→ Go to D11 and code '0' → D7	
to sleep.	At least 1 hr but less than 3 hrs 3 hrs or more	2	→ D6	
3 or more hours trying	ow many nights did you spend g to get to sleep? 4 nights or more 1 to 3 nights None	1 2 3	-	
	find you can't get back to sleep? Yes No	1 2	$\rightarrow D10$	
D8 Informants who slep	t more than usual			
Thinking about the ni how much longer did normally sleep for?	ght you slept the longest in the past week, you sleep compared with how long you Less than 1/4 hr	3	→ Go to D11 and code '0'	
	At least 1/4 hr but less than 1 hr At least 1 hr but less than 3 hrs 3 hrs or more	1 2 2	\rightarrow D10 \rightarrow D9	
D9 In the past week, on h than 3 hours longer th	ow many nights did you sleep for more an you usually do? 4 nights or more 1 to 3 nights None	1 2 3		

D10 How long have you had sleep as you have descri			
Show card 2	 less than 2 weeks 2 weeks but less than 6 months 6 months but less than 1 year 1 year but less than 2 years 2 years or more 	1 2 3 4 5	
D11 Interviewer check: Sum codes which you I shaded boxes at D3, D5		0	+ Insert score on Check card, then go to section E

* E Irritability		r	7
E1 Many people become irritable or short tem though they may not show it.	pered at times,		
Have you felt irritable or short tempered w around you in the past month?	ith those		
	Yes/no more than usual	1	→ E3
	No	2	\rightarrow E2
E2 During the past month did you get short ter over things which now seem trivial when y on them?	mpered or angry rou look back		-
	Yes	1	→ E3
	No	2	→ Go to section F
E3 Since last (DAY OF WEEK), on how many you felt irritable or short tempered/angry?	y days have		-
	4 days or more	1	F4
	1 to 3 days	2	
	None	3	→ E11
E4 What sort of things made you irritable or sl in the past week?	hort tempered/angry		
E5 In total, have you felt irritable or short tem more than one hour (on any day in the past	pered/angry for week)?		-
	Yes	1	
	No	2	
E6 During the past week, have you felt so irritable or short tempered/angry that you have wanted to shout at someone, even if you haven't actually shouted?	Yes No	1 2	

E7	In the past seven days, hav or quarrels or lost your ter		ows		
			Yes	1	→ (a)
			No	2	→ E10
	(a) Did this happen once (in the past week)?	or more than once			
			Once	1	→ E8
			More than once	2	→ E9
E8	Do you think this was just	ified?			
			Yes, justified	2	
			No, not justified	1	→E10
FO	Do you think this was just	ified on every econoion?			
E9	Do you think this was just	med on every occasion?			
		Yes		2	F10
		No, at least one was u	njustified	1	
E1(How long have you been short tempered/angry as	feeling irritable or you have described ?			
	Show card 2	less than 2 weeks		1	
		two weeks but less that	an 6 months	2	
		6 months but less than	1 year	3	
		1 year but less than 2	years	4	
		2 years or more		5	
E1 1	Interviewer check:				
	Sum codes which you h shaded boxes at E3, E5	nave ringed in the , E6, E8 and E9.			
		Ring '0' if	f sum of codes is zero	0	Г П
		or			→Insert score
		enter scor	re→		on Check card, then go to section F
					l

* F Worry about physical h	ealth		1
F1 Many people get concerned health. In the past month, h worried about your physica	ave you been at all		
Include women who are worried about the	Yes, worried	1	→ F3
pregnancy	No/concerned	2	→F2
F2 Informants who have no p	roblems with physical health		
DNA	:has a physical health problem shown at 11a <u>page 6</u>	1	→ Go to section G
During the past month, did that you might have a serior	you find yourself worrying is physical illness?		
	Yes	1	→F3
	No	2	→Go to section G
F3 Thinking about the past seven days, including last (DAY OF WEEK), on how many days have you found yourself worrying about your physical health/that you might have a serious physical illness?			
	4 days or more	1	
	1 to 3 days	2	F4
	None	3	→ F8
F4 In your opinion, have you b view of your actual health?	een worrying too much in		
	Yes	1	
	No	2	
F5 In the past week, has this w	orrying been		
D	very unpleasant	1	
Running prompt	a little unpleasant	2	
	or not unpleasant?	3	

F6		been able to take your mind off t once, by doing something else?		
		Yes	2	
		No, could not be distracted once	1	
F7	How long have you been w health in the way you have	orrying about your physical described?		
	Show card 2	less than 2 weeks	1	
	Show card 2	2 weeks but less than 6 months	2	
		6 months but less than 1 year	3	
		1 year but less than 2 years	4	
		2 years or more	5	
F8	Interviewer check:			
	Sum codes which you hav shaded boxes at F3, F4, F			
		Ring '0' if sum of codes is zero	0]
		or		→Insert score on Check card,
		enter score		then go to section G

* G Depression

			1
at times.	ecomes sad, miserable or depressed Il of feeling sad, miserable or depressed		
	Yes	1	
	No	2	
G2 During the past mo or take an interest i	nth, have you been able to enjoy n things as much as you usually do?		
	Yes	1	
	No/no enjoyment or interest	2	
G3 Interviewer check	:		
Code first that	Informant felt sad, miserable or depressed (coded 1 at G1)	1	→ G4
applies	Informant unable to enjoy or take an interest (coded 2 at G2)	2	→ G5
	Others	3	→ Go to Section I, page 28
G4 In the past week hat sad, miserable or de	ve you had a spell of feeling epressed?		r-8
Use informant's own words if possible	Yes	1	→See G5
possible	No	2	
G5 Informants who w an interest in thing	ere unable to enjoy or take gs		
	DNA: coded 1 at G2	1	→ See G6
In the past week has or take an interest i	ave you been able to enjoy n things as much as usual?		
Use informant's	Yes	2	
own words if possible	No/no enjoyment or interest	1	

	G4 or G5) DNA: others		1	→Go to G
	AY OF WEEK) on how many days have you felt le or depressed/unable to enjoy or take an interest			
in unigs:	4 days or more		1	
	2 to 3 days		2	
	1 day		3	
interest in th	t le or depressed/unable to enjoy or take an ings for more than 3 hours in total in the past week)? Yes		1	
20 () WH	No		2	
sad, mis	rts of things made you feel erable or depressed/unable to enjoy or take est in things in the past week? Can you choose s card?			
nom un		(a)	(b)	
Ring co	de(s) in column (a).	Code all that apply	Code one only	
	Members of the family	01	01	
	Relationship with spouse/partner	02	02	
	Relationships with friends	03	03	
Show card 5			03 04	
Show card 5		04		
Show card 5	Housing	04 05	04	
Show card 5	Housing	04 05	04 05	
Show card 5	Housing Money/bills Own physical health (inc. pregnancy)	04 05 06 07	04 05 06	
Show card 5	Housing Money/bills Own physical health (inc. pregnancy) Own mental health	04 05 06 07 08	04 05 06 07	
Show card 5	Housing Money/bills Own physical health (inc. pregnancy) Own mental health Work or lack of work (inc. student)	04 05 06 07 08	04 05 06 07 08	
Show card 5	Housing Money/bills Own physical health (inc. pregnancy) Own mental health Work or lack of work (inc. student) Legal difficulties	04 05 06 07 08 09	04 05 06 07 08 09	
Show card 5	Housing Money/bills Own physical health (inc. pregnancy) Own mental health Work or lack of work (inc. student) Legal difficulties Political issues/the news	04 05 06 07 08 09 10	04 05 06 07 08 09 10	

G9 In the past week when sad, miserable or depro- did you ever become h or when you were in c	essed/unable to enjoy or take an interest in things, appier when something nice happened,		
	Yes, at least once	2	
	No	1	
G10 How long have you b sad, miserable or depr interest in things as y	essed/unable to enjoy or take an		
	less than 2 weeks	1	
Show card 6	2 weeks but less than 6 months	2	
	6 months but less than 1 year	3	
	1 year but less than 2 years	4	
	2 years or more	5	
G11 Interviewer check:			
Sum codes which yo shaded boxes at G5,			
	Ring '0' if sum of codes is zero	0	7
	or		+Insert score
	enter score		on Check card, then go to section H

* H Depressive Ideas H1 Informants who scored 1 or more at section G, Depression DNA: Others (coded O or blank at G11) 1 +Go to section I I would now like to ask you about when you have been feeling sad, miserable or depressed/unable to enjoy or take an interest in things. In the past week, was this worse in the morning or in the evening, or did this make no difference? in the morning 1 Prompt as 2 in the evening necessary no difference/other 3 H2 Ask or use card 7 Many people find that feeling sad, miserable or depressed/unable to enjoy or take an interest in things can affect their interest in sex. Over the past month, do you think your interest in sex has increased 1 Running 2 decreased prompt or has it stayed the same? 3 4 Spontaneous Not applicable H3 When you have felt sad, miserable or depressed/unable to enjoy or take an interest in things in the past seven days, Yes No have you been so restless that you couldn't sit still?..... 2 1 Individual have you been doing things more slowly, prompt for example, walking more slowly? 1 2 have you been less talkative than normal? 2 1 H4 Now, thinking about the past seven days have you on at least one occasion felt guilty or blamed yourself when things went wrong when it hasn't been your fault? Yes, at least once 1 No 2 H5 During the past week, have you been feeling you are not as good as other people? Yes 1 No 2 H6 Have you felt hopeless at all during the past seven days, for instance about your future? Yes 1 No

H7 Interviewer check

		1
Informant felt guilty, not as good as others or hopeless (coded 1 at H4 or H5 or H6)	1	→ H8
Others (coded 2 at H4, H5 and H6)	2	→ read H10
H8 Ask or use card 8		-
In the past week have you felt that life isn't worth living?		
Yes	1	→ H9
Spontaneous: Yes, but not in the past week	2	
No	3	i→ read H10
		-
H9 Ask or use card 9		
In the past week, have you thought of killing yourself?		
Yes	1	→ (a)
Spontaneous: Yes, but not in the past week	2	
No	3	→ read H10
(a) Have you talked to your doctor about these thoughts (of killing yourself)?		
Yes	1	→ read H10
Spontaneous: No, but has talked to other people	2	
No	3	read (b)
(b) (You have said that you are thinking about committing suicide.)Since this is a very serious matter it is important that you talk to your doctor about these thoughts.		
		→ read H10
H10 (Thank you for answering those questions on how you have been feeling. I would now like to ask you a few questions about worrying.)		-
H11 Interviewer check:		
Sum codes which you have ringed in the shaded boxes at H4, H5, H6, H8 and H9.		
Maximum score Ring '0' if sum of codes is zero	0	Insert score on Check card,
on this section or is 5		then go to section I
enter score		<u></u>

* I Worry

I 1 (The next few quest In the past month, d you needed to abou	ions are about worrying.) id you find yourself worrying more t t things?	han			
	Yes	worrying		1	→I3
	No/o	oncerned		2	\rightarrow 12
I 2 Have you had any w	vorries at all in the past month?				
	Yes			1	→I3
	No .			2	Go to
					section J
I3 (a) Can you look a	t this card and tell me what sorts				
	vorried about in the past month?	Ĺ	(a)	(b)	
Ring code(s) in	n column (a).		Code all that apply	Code one only	
	Members of the family		01	01	
	Relationship with spouse/pa	rtner	02	02	
Show card 10	Relationships with friends .		03	03	
	Housing		04	04	
	Money/bills		05	05	
	Own physical health (inc. pre	gnancy)	06	06	
	Own mental health		07	07	
	Work or lack of work (inc s	tudent).	08	08	
	Legal difficulties		09	09	
	Political issues/the news		10	10	
	Other		11	11	
	Don't know/no main thing	L	99	99	
(b)	DNA : Only one item coded at (a)		1	→ I4
What was the n Ring code in c	nain thing you worried about? olumn (b).				
I 4 Interviewer check	:				Г., .
Informant worries about physical health (coded 06 at I3(a))					See instruction below, then go to I5
Oth	ners (not coded 06 at I3(a))			2	→I6
Make a note on Cl	eck flap to go to section F to recor	d this			

I 5	Interviewer check:			
	Informant (only co	t is only worried about physical health ode 06 is rung at I3(a))	1	→ Go to section J
	Informant	t had other worries (I3(a) is multi-coded)	2	→ read (a)
	(a) For the next few ques about the worries you about your physical h	have had other than those		
I 6	On how many of the past s worrying about things (oth	seven days have you been her than your physical health)?		
		4 days or more	1	
		1 to 3 days	2	→I7
		None	3	→I 11
I 7	In your opinion, have you in view of your circumstar	been worrying too much nces?		
г		Yes	1	
	Refer to worries other than those about physical health	No	2	
18	In the past week, has this	worrying been:		
	D	very unpleasant	1	
	Running prompt	a little unpleasant	2	
	Refer to worries other than those about physical health	or not unpleasant?	3	
19	Have you worried for mor on any one of the past seve			
г		Yes	1	
	Refer to worries other than those about physical health	No	2	
				J

I 10 How long have you been in the way that you have o			
Show card 11	 less than 2 weeks 2 weeks but less than 6 months 6 months but less than 1 year 1 year but less than 2 years 	1 2 3 4	
	2 years or more	5	
I 11 Interviewer check:			
Sum codes which you have ringed in the shaded boxes at I6, I7, I8 and I9.			
	Ring '0' if sum of codes is zero	0]
	or enter score		→ Insert score on Check card, then go to section J

*	J Anxiety	r	7
J1	Have you been feeling anxious or nervous in the past month?		
	Yes, anxious or nervous	1	→ J3
	No	2	\rightarrow J2
J2	In the past month, did you ever find your muscles felt tense or that you couldn't relax?		-
	Yes	1	
	No	2	
J3	Some people have phobias; they get nervous or uncomfortable about specific things or situations when there is no real danger. For instance they may get nervous when speaking or eating in front of strangers, when they are far from home or in crowded rooms, or they may have a fear of heights. Others become nervous at the sight of things like blood or spiders.		
	In the past month have you felt anxious, nervous or tense about any specific things or situations when there was no real danger?		
	Yes	1	
	No	2	
J4	Interviewer check:		-
	Informant reports anxiety and also a phobia (coded 1 at J1 or J2, and coded 1 at J3)	1	→ J5
	Informant reports only general anxiety (coded 1 at J1 or J2, and coded 2 at J3)	2	→ J7
	Others	3	→ Go to section K
J5	In the past month, when you felt anxious/nervous/tense, was this always brought on by the phobia about some specific situation or thing or did you sometimes feel generally anxious/nervous/tense?		-
	Always brought on by phobia	1	→ Go to section K
	Sometimes felt generally anxious	2	→ J6

J6	anxiety/nervousnes I will ask you abou	are concerned with general s/tension only. t the anxiety which is brought bout specific things or situations later.		
	On how many of th have you felt gener	e past seven days rally anxious/nervous/tense?		
		4 days or more	1	
		1 to 3 days	2	J →J8
		None	3	→ J12
J7	On how many of th generally anxious/r	e past seven days have you felt hervous/tense?		
		4 days or more	1	
		1 to 3 days	2	→ J8
		None	3	→J12
J 8	In the past week, has anxiety/nervousnes			
	Running	very unpleasant	1	
	prompt	a little unpleasant	2	
		or not unpleasant?	3	
J9		hen you've been anxious/nervous/tense, f the symptoms shown on this card?		
	Sham and 12	Yes	1	→(a)
	Show card 12	No	2	→ J10
	(a) Which of these anxious/nervo	e symptoms did you have when you felt		_
		Heart racing or pounding	1	
	Code all that apply	Hands sweating or shaking	2	
	that appry	Feeling dizzy	3	
		Difficulty getting your breath	4	
		Butterflies in stomach	5	
		Dry mouth	6	
		Nausea or feeling as though you wanted to vomit	7	
				_

If informant had any of these symptoms, check J9 is coded 1, 'Yes'.

J10	Have you felt anxious/ne than 3 hours in total on a	ervous/tense for more any one of the past seven days?		
		Yes	1	
		No	2	
J11	How long have you had anxiety/nervousness/tens			
	Share and 11	less than 2 weeks	1	
	Show card 11	2 weeks but less than 6 months	2	
		6 months but less than 1 year	3	
		1 year but less than 2 years	4	
		2 years or more	5	
J12	Interviewer check:			
	Sum codes which you h shaded boxes at J6, J7,			
		Ring '0' if sum of codes is zero	0	1
		or		+Insert score
		enter score		on Check card, then go to section K

			I
K1 Interviewer checl	k:		
Informants who ha	ad phobic anxiety in the past month (coded 1 at J3)	1	→ K3(a)
Others		2	\rightarrow K2
			_
the have a phobia	avoid a specific situation or thing because about it. For instance, some people avoid		
would make them	avoid going to busy places because it feel nervous or anxious.		
thing because it w	have you avoided any situation or ould have made you feel nervous ough there was no real danger?		
,	Yes	1	→ K3(b)
	No	2	→ See section L
	10	2	- See section E
the situations o	t this card and tell me which of r things listed made you the most		
	s/tense in the past month? b), then go to K4		
Show card 13			
	t this card and tell me, which of or things did you avoid the most th?		
Show card 13			
	Crowds or public places, including travelling alone or being far from home	1	
Code one	Enclosed spaces	2	
only	Social situations, including eating or speaking in public, being watched or stared at	3	
	The sight of blood or injury	4	
	Any specific single cause including insects, spiders and heights	5	
	Other (specify)	6	
			-
K4 Informants who l	nad phobic anxiety in past month		
	DNA: others (coded 2 at K1)	1	→ K7
In the past seven d	ays, how many times have you		
felt nervous or any	cious about (SÍTUATION/THING)?		
	4 times or more	1	⊣ к5
	1 to 3 times	2	
	None	3	→ K6

КЭ	In the past week, on those anxious/nervous/tense did	occasions when you left you have any of the		
	symptoms on this card?	Yes	1	 →(a)
ſ	Show card 12	No	2	→K6
(a)	Which of these symptoms			-
	anxious/nervous/tense?	Heart racing or pounding	1	
	Code all	Hands sweating or shaking	2	
	that apply	Feeling dizzy	3	
		Difficulty getting your breath	4	
	If informant had any of	Butterflies in stomach	5	
	these symptoms, check K5 is coded 1, 'Yes'.	Dry mouth	6	
	K5 is coucu 1, 1 cs .	Nausea or feeling as though you wanted to vomit	7	
K6	it would have made you fee	avoided any situation or thing because el anxious/nervous/tense even though		-
	there was no real danger?	Yes	1	→ K7
		No	2	→ K8
K7		r avoided such situations or things		
	in the past seven days?	1 to 3 times	1	
		4 times or more	2	
		None	3	
K8	Informants who had phol past week (coded 1 or 2 a	bic anxiety/avoidance in the it K4 or K7)		-
		DNA: others	1	→K9
	How long have you been h situations/things as you have	aving these feelings about these ve just described?		
		less than 2 weeks	1	
	Show card 14	2 weeks but less than 6 months	2	
		6 months but less than 1 year	3	
		1 year but less than 2 years	4	
		2 years or more	5	
K9	Interviewer check:			-
	Sum codes which you ha shaded boxes at K4, K5	we ringed in the and K7.		
		Ring '0' if sum of codes is zero	0	Insert score
		or		then see section L

* L Panic

				1
1 Informants who f	celt anxious in the past m	ionth		
	DNA: Others (coded	l 3 at J4, page 31)	1	→ Go to section M
Thinking about the bad that you got in collapse or lose con				
		Yes	1	→L2
		No	2	→ Go to section M
2 How often has this	s happened in the past wee	ek?		
		Once	1	→L3
		More than once	2	
		Not at all	3	→L8
3 In the past week, h	nave these feelings of pani	c been:		
Running	a little uncomfo	ortable or unpleasant	2	
prompt	or have they been unbearable?	very unpleasant or	1	
4 Did this panic/they than 10 minutes?	worst of these panics last	for longer		
		Yes	1	
		No	2	
5 Are you relatively	free of anxiety between th	-		
5 Are you relatively	free of anxiety between th	Yes	1	
5 Are you relatively	free of anxiety between th	-	1 2	

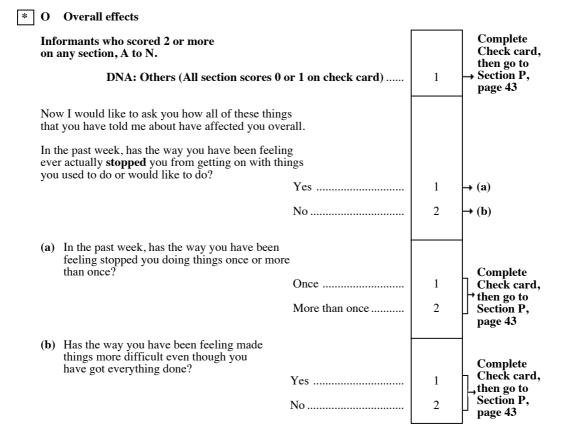
L6	Informants who had pho			
		DNA: Others (coded 2 at K1)	1	→L7
	Refer to situation/thing a			
	Is this panic always broug			
		Yes	1	
		No	2	
L7	How long have you been as you have described?	having these feelings of panic		
		less than 2 weeks	1	
	Show card 14	2 weeks but less than 6 months	2	
		6 months but less than 1 year	3	
		1 year but less than 2 years	4	
		2 years or more	5	
L8	Interviewer check:			
	Sum codes which you ha shaded boxes at L2, L3,			
		Ring '0' if sum of codes is zero	0	7
			+Insert score	
		enter score		on Check card, then go to section M

* M Compulsions M1 In the past month, did you find that you kept on doing things over and over again when you knew you had already done them, for instance checking things like taps or washing yourself when you had already done so? 1 → M2 Yes 2 No • Go to section N M2 On how many days in the past week did you find yourself doing things over again that you had already done? 4 days or more 1 •M3 1 to 3 days 2 3 → M9 None M3 Since last (DAY OF WEEK) what sorts of things have you done over and over again? M4 During the past week, have you tried to stop yourself repeating (BEHAVIOUR)/doing any of these things over again? 1 Yes 2 No M5 Has repeating (BEHAVIOUR)/doing any of these things over again made you upset or annoyed with yourself in the past week? Yes, upset or annoyed 1 No, not at all 2

M6 If more than one thing is	repeated at M3		
	1	→ M7	
Thinking about the past we mentioned did you repeat	eek, which of the things you the most times?		
Des	cribe here		→ M7
M7 Since last (DAY OF WEE repeat (BEHAVIOUR) wh			
	3 or more repeats	1	
Refer to BEHAVIOUR at M6, if applicable	2 repeats	2	
	1 repeat	3	
M8 How long have you been r (BEHAVIOUR)/any of the in the way which you have	e things you mentioned		
Show card 14	less than 2 weeks	1	
Show card 14	2 weeks but less than 6 months	2	
	6 months but less than 1 year	3	
	1 year but less than 2 years	4	
	2 years or more	5	
M9 Interviewer check:			
Sum codes which you ha shaded boxes at M2, M4,	ve ringed in the M5 and M7.		
	Ring '0' if sum of codes is zero	0	
	or		+ Insert score
	enter score		☐ on Check card, ☐ then go to section N

	IN OUSCSSIUMS		
N1	In the past month did you have any thoughts or ideas over and over again that you found unpleasant and would prefer not to think about, that still kept on coming into your mind?		
	Yes	1	→ N2
	No	2	→ Go to section O
N2	Can I check, is this the same thought or idea over and over again or are you worrying about something in general?		
	Same thought	1	→ N3
	Worrying in general	2	→ See
	Make a note on check flap to go to section I to record this worry, if not already recorded.		instruction below, then go to section O
N3	What are these unpleasant thoughts or ideas that keep coming into your mind?		
	Do not probe Do not press for answer		
N4	Since last (DAY OF WEEK), on how many days have you had these unpleasant thoughts?		
	4 days or more	1	
	1 to 3 days	2	→N5
	None	3	→ N9
N5	During the past week, have you tried to stop yourself thinking any of these thoughts?		
	Yes	1	
	No	2	
N6	Have you become upset or annoyed with yourself when you have had these thoughts in the past week?		
	Yes, upset or annoyed	1	
	Not at all	2	

N7	In the past week, was the lo thoughts :	ongest episode of having such		
	Running prompt or	a quarter of an hour or longer	1	
N8	How long have you been h in the way which you have			
	Show card 14	less than 2 weeks	1	
	Show card 14	2 weeks but less than 6 months	2	
		6 months but less than 1 year	3	
		1 year but less than 2 years	4	
		2 years or more	5	
N9	Interviewer check:			
	Sum codes which you hav shaded boxes at N4, N5, N			
		Ring '0' if sum of codes is zero	0	7
		or		+Insert score
		enter score		on Check card, then go to section O



APPENDIX L: MEAN SCORES PER PUSKESMAS

Puskesm	as	CIS-R BL	CIS-R FU	HoNOS BL	HoNOS FU	WHODAS BL	WHODAS FU	EQ5D3L Msia BL	EQ5D3L Msia FU
Sevegan	Mean (SD)	29.00 (14.90)	8.25 (3.86)	14.00 (11.11)	6.25 (4.79)	11.44 (6.47)	12.73 (3.96)	0.80 (0.23)	0.84 (0.14)
(N=4)	Median	31	8.5	14	6	9.20	12.26	0.80	0.83
	Range	12 - 42	4 - 12	3 - 25	1 - 12	6.6 - 20.75	8.49 - 17.92	0.6 - 1	0.72 - 1
	Mean	17.25	6.25	3.75	4.88	27.47			()
Ngemplak I	(SD)	(10.98)	(6.63)	(2.61)	(5.87)	(17.93)	22.22 (17.14)	0.71 (0.09)	0.76 (0.05)
(N=8)	Median	13.5	4.5	3	3	21.22	20.99	0.75	0.75
	Range	4 - 38	0 - 20	1-9	0 - 18	8.49 - 58.7	0 - 42.39	0.55 - 0.8	0.71 - 0.86
Ngaglik II	Mean (SD)	19.11 (22.58)	0.45 (1.04)	4.26 (3.40)	2.45 (3.53)	24.93 (14.12)	7.79 (11.53)	0.70 (0.17)	0.81 (0.16)
(N ₀ =19,	Median	12	0	4	0	21.70	1.4151	0.75	0.87
N ₁ =11)			0-3		0-9				
	Range Mean	3 - 100	3.73	0 - 11 5.14	3.09	3.77 - 49.06 21.99	0 - 32.61	0.3 - 1	0.42 - 1
Umbulharjo I	(SD)	6.93 (5.77)	(2.97)	(3.90)	(3.27)	(19.23)	3.33 (5.20)	0.84 (0.09)	0.89 (0.06)
(N ₀ =14,	Median	5	3	4.5	3	14.15	1.09	0.80	0.87
N ₁ =11)	Range	1 - 22	0 - 8	0 - 11	0 - 9	2.83 - 58.49	0 - 15.09	0.68 - 1	0.8 - 1
	Mean		3.54	5.63	2.69				
Kota Gede I	(SD)	8.63 (9.14)	(4.82)	(5.23)	(2.29)	45.24 (18.8)	21.47 (19.07)	0.78 (0.12)	0.86 (0.07)
(N ₀ =16,	Median	5	2	4	2	43.36	30.19	0.82	0.85
N ₁ =13)						14.15 -			
	Range Mean	1 - 32 14.50	<u>0 - 17</u> 4.50	0 - 18 4.33	0-6	87.74 24.81	0 - 50.94	0.53 - 1	0.72 - 0.95
Gondomanan	(SD)	(5.58)	(5.36)	(4.50)	(2.04)	(15.05)	8.69 (11.94)	0.77 (0.16)	0.82 (0.11)
(N=6)	Median	15	3	3.5	2	26.41	4.71	0.80	0.83
(Range	7 - 23	0 - 14	0 - 11	0 - 5	4.72 - 43.48	0 - 30.43	0.55 - 1	0.66 - 0.93
	Mean		2.00	7.50	1.75	18.41			
Rongkop	(SD)	9.25 (8.22)	(2.83)	(5.07)	(2.06)	(13.27)	3.07 (6.13)	0.79 (0.23)	0.83 (0.15)
(N=4)	Median	7	1	8.5	1.5	14.15	0	0.84	0.84
	Range	2 - 21	0 - 6	1 - 12	0 - 4	7.61 - 37.74	0 - 12.26	0.47 - 1	0.65 - 1
	Mean	10.36	5.50	7.57	3.71			0.00 (0.00)	a aa (a aa)
Karangmojo II	(SD)	(10.54)	(6.44)	(5.27)	(4.38)	13.63 (7.40)	10.06 (9.44)	0.80 (0.06)	0.83 (0.08)
(N=14)	Median	4	2	6.5	2.5	14.14	9.91	0.80	0.81
	Range	1 - 31	<u>0 - 19</u> 4.94	0 - 18 5.65	0 - 16 2.23	3.77 - 23.91 37.81	0 - 33.02	0.66 - 0.88	0.66 - 0.95
Jetis II	Mean (SD)	3.00 (2.62)	(5.96)	(6.93)	(2.09)	(14.44)	17.47 (16.55)	0.80 (0.10)	0.84 (0.08)
(N ₀ =17,	Median	3	3	3	2	34.78	15.09	0.80	0.86
N ₁ =16)	Range	0 - 9	0 - 22	0 - 23	0 - 5	11.32 - 75	0 - 47.17	0.48 - 1	0.67 - 1
	Mean		3.25	1.50	3.75				
Sedayu II	(SD)	4.50 (2.65)	(3.78)	(1.00)	(2.63)	9.34 (8.88)	16.76 (11.28)	0.87 (0.10)	0.89 (0.07)
(N=4)	Median	5	3	2	4.5	8.78	21.24	0.83	0.90
	Range	1-7	0 - 7	0 - 2	0 - 6	0 - 19.81	0 - 24.53	0.8 - 1	0.8 - 0.95
	Mean (SD)	21.70	7.33	7.70	5.44	20.97	10.80 (20.00)	0.80 (0.00)	0.97 (0.07)
Srandakan	(SD)	(9.09)	(7.07)	(3.80)	(5.41)	(12.33)	19.80 (20.09)	0.80 (0.09)	0.87 (0.07)
(N ₀ =10, N ₁ =9)	Median	19.5	5	7	6	18.40	15.09	0.80	0.87
	Range Mean	8 - 39 10.21	0 - 20 4.68	1 - 15 2.42	0 - 17 3.16	7.55 - 42.45 16.91	0 - 47.83	0.68 - 1	0.79 - 1
Temon I	(SD)	(8.62)	(4.20)	(2.61)	(4.00)	(12.91)	9.80 (11.06)	0.76 (0.18)	0.81 (0.16)
(N=19)	Median	7	5	2	2	15.09	3.77	0.80	0.80
(15)	Range	2 - 33	0 - 15	0 - 8	0 - 17	0 - 45.65	0 - 39.13	0.39 - 1	0.51 - 1
	Mean	_ 00	3.78	4.70	2.39	31.91	0 00110		
Wates	(SD)	7.70 (9.10)	(3.59)	(3.07)	(2.55)	(16.97)	3.95 (5.88)	0.76 (0.15)	0.83 (0.12)
(N ₀ =23,	Median	5	4	4	1.5	32.61	0	0.80	0.83
N ₁ =18)	Range	0 - 40	0 - 12	1 - 11	0 - 9	6.6 - 56.6	0 - 18.87	0.47 - 1	0.56 - 1
	Mean		6.63	2.13	5.12	22.31			
Kalibawang	(SD)	2.00 (1.51)	(10.21)	(1.86)	(8.41)	(17.19)	15.07 (14.60)	0.71 (0.13)	0.75 (0.11)
(N=16)	Median	2	1	1.5	2.5	14.14	9.60	0.73	0.75
	Range	0-6	0 - 37	0-6	0-33	5 12 - 58 19	0 - 49 06	0 38 - 0 85	0 56 - 0 92

Puskesm	ias	CIS-R BL	CIS-R FU	HoNOS BL	HoNOS FU	WHODAS BL	WHODAS FU	EQ5D3L Msia	EQ5D3L Msia
								BL	FU
	Mean	0.40 (0.80)	1.00	5.80	1.20		2.00 (5.64)	0.02 (0.07)	
Moyudan	(SD)	0.40 (0.89)	(1.41)	(2.68)	(0.84)	6.15 (4.57)	2.99 (5.64)	0.92 (0.07)	0.95 (0.05)
(N=5)	Median	0	0	7	1	5.66	0.94	0.88	0.95
	Range	0 - 2	0 - 3	2 - 8	0 - 2	2.17 - 13.21	0 - 13.04	0.85 - 1	0.88 - 1
	Mean (SD)	12.44	4.25	5.78	2.75	26.35	0 04 (14 11)	0.80 (0.17)	0.94 (0.15)
Minggir		(7.83)	(4.13)	(3.38)	(2.38)	(21.18)	8.84 (14.11)	0.80 (0.17)	0.84 (0.15)
(N ₀ =9, N ₁ =8)	Median	12	3.5	5	2.5	17.92	2.35	0.85	0.88
	Range	3 - 22	0 - 13	1 - 12	0-6	3.77 - 64.13	0 - 41.3	0.4 - 1	0.51 - 1
.	Mean (SD)	19.50 (4.32)	2.00 (3.35)	10.50 (4.09)	1.67 (2.73)	16.56 (12.10)	1.09 (2.17)	0.76 (0.10)	0.83 (0.10)
Gamping I					0.5	(12.10)			
(N=6)	Median	22	0	10			0	0.77	0.82
	Range	13 - 23	0 - 8	6 - 16	0-7	5.43 - 36.79	0 - 5.43	0.59 - 0.88	0.71 - 0.95
Mlati II	Mean (SD)	10.45 (10.10)	2.60 (4.90)	5.09 (4.06)	3.00 (5.83)	22.30 (13.50)	10.91 (5.73)	0.78 (0.11)	0.81 (0.10)
(N ₀ =11,		7	0	4	0.5				
N ₁ =10)	Median					17.92	12.73	0.80	0.80
	Range Mean	1 - 30 11.11	0 - 15 3.47	1 - 13 3.84	0 - 17 2.95	5.43 - 46.23 31.89	0 - 16.98	0.55 - 1	0.67 - 1
Donald	(SD)	(7.26)	(3.55)	(5.41)	(3.21)	(14.90)	16.69 (14.58)	0.81 (0.13)	0.85 (0.13)
Depok II (N-19)	Median	10	2	2	3	34.90	20.75	0.83	0.87
(N=19)									
	Range Mean	1 - 30	0 - 15	0 - 23 4.18	0 - 14 2.43	7.55 - 56.52 26.30	0 - 38.68	0.56 - 1	0.45 - 1
Darkak	(SD)	9.36 (9.26)	(4.58)	(4.36)	(4.24)	(17.80)	8.49 (13.14)	0.76 (0.12)	0.79 (0.11)
Berbah	Median	8	1	3	0	21.73	2.83	0.80	0.79
(N ₀ =11, N ₁ =8)					0 - 10				0.62 - 1
	Range Mean	0 - 32 13.94	0 - 13	0 - 14 9.50	6.00	3.77 - 52.83 35.22	0 - 36.79	0.6 - 1	0.62 - 1
Kalasan	(SD)	(10.51)	(7.75)	(7.38)	(6.54)	(15.06)	29.64 (15.38)	0.74 (0.15)	0.78 (0.10)
(N ₀ =18,	Median	13	6	7.5	3	31.52	30.43	0.77	0.80
N ₁ =15)			0 - 30						
	Range Mean	2 - 38 11.32	2.32	1 - 25 7.32	0 - 22 2.53	5.66 - 66.04	2.83 - 52.83	0.44 - 1	0.63 - 1
Sleman	(SD)	(7.16)	(2.93)	(4.37)	(3.01)	17.34 (8.68)	2.36 (3.94)	0.77 (0.09)	0.82 (0.08)
(N=19)	Median	11	0	7	1	18.86	0	0.80	0.80
(((-15))	Range	1 - 26	0 - 8	1 - 17	0 - 8	3.77 - 33.02	0 - 10.38	0.54 - 0.88	0.66 - 0.95
	Mean	15.80	6.00	11.00	3.60	19.57	0 - 10.58	0.54 - 0.88	0.00 - 0.55
Kota Gede II	(SD)	(13.92)	(8.03)	(8.75)	(4.83)	(14.73)	17.04 (17.28)	0.79 (0.16)	0.83 (0.13)
(N=5)	Median	8	3	7	2	15.09	16.98	0.85	0.85
(11-3)	Range	5 - 37	0 - 20	4 - 25	0 - 12	4.35 - 43.48	0 - 38.04	0.62 - 1	0.62 - 1
	Mean	16.25	7.47	5.50	6.53	20.39	0-38.04	0.02 - 1	0.02 - 1
Danurejan I	(SD)	(17.43)	(7.35)	(7.09)	(7.66)	(18.48)	16.33 (14.98)	0.88 (0.09)	0.88 (0.09)
(N ₀ =16,	Median	13	5	2.5	6	12.26	11.95	0.88	0.88
N ₁ =15)	Range	1 - 72	0 - 28	0 - 22	0 - 30	0.94 - 47.83	0 - 50	0.66 - 1	0.63 - 1
	Mean		1.80	1.80	2.80	19.06			
Danurejan II	(SD)	1.60 (1.34)	(2.49)	(2.49)	(5.22)	(10.99)	9.25 (6.31)	0.87 (0.08)	0.89 (0.09)
(N=5)	Median	1	1	1	0	17.92	8.49	0.85	0.92
/	Range	0 - 3	0 - 6	0 - 6	0 - 12	7.55 - 36.79	2.83 - 18.87	0.8 - 1	0.8 - 1
	Mean	19.29	6.86	9.71	3.14		2.00 10.07	1	0.0 1
Ngampilan	(SD)	(4.89)	(5.40)	(5.53)	(1.95)	15.42 (7.03)	16.58 (16.82)	0.76 (0.11)	0.76 (0.14)
(N=7)	Median	20	5	10	3	14.15	10.37	0.80	0.72
. ,	Range	12 - 27	0 - 17	1 - 18	0 - 6	7.55 - 29.25	0.94 - 52.83	0.57 - 0.85	0.55 - 0.92
	Mean	10.55	3.79	5.50	3.00	23.20			
Jetis	(SD)	(10.08)	(3.47)	(4.82)	(3.05)	(16.08)	12.20 (11.11)	0.80 (0.14)	0.84 (0.13)
(N ₀ =20,	Median	7.5	4	4.5	2	20.75	11.32	0.85	0.87
N ₁ =19)	Range	1 - 39	0 - 13	1 - 18	0 - 12	4.35 - 53.77	0 - 35.87	0.37 - 1	0.49 - 1
	Mean	11.17	4.43	5.59	3.45	24.77			
Total	(SD)	(11.36)	(5.49)	(5.26)	(4.49)	<mark>(16.75)</mark>	12.46 (13.99)	0.78 (0.13)	0.83 (0.11)
(N ₀ =325,	Median	8	3	4	2	19.81	8.49	0.80	0.85
N ₁ =294)	Range	0 - 100	0 - 37	0 - 25	0 - 33	0 - 87.74	0 - 52.83	0.3 - 1	0.42 - 1
	nunge	0 - 100	0 37	0 25	0.33	0-07.74	0 32.03	0.3 - 1	0.42 - 1

APPENDIX M: PUBLISHED WHO MHGAP LITERATURE

Table 26. Summary of Literature Describing WHO mhGAP Training (Keynejad et al., 2018)

Authors/ Country	Design	Participants/ Sample Size	Intervention Details	Evaluation Details	Summary of Findings
Adebowale 2014 Nigeria	Quasi-experimental study. 3-day training course developed from mhGAP-IG. Aimed to improve diagnosis and management of priority conditions: Psychosis, Depression, Alcohol & Substance abuse, Epilepsy and Other Significant Emotional Complaints (OSEC). Knowledge and skills to diagnose and treat mental health case vignettes assessed pre and post-course.	Primary Health Care (PHC) Workers 80 90% female 88% nurses	4 PHC workers nominated by 20 localgovernment areas, based on interest.Collaboration with mental health professionals interested in PHC from Lancashire Care NHS Foundation Trust/University of Manchester under a British Council Health Link Scheme. Written support materials included locally adapted assessment flow charts, case records, follow-up sheets to guide and record practice. 3 day training course delivered as a 1 day introductory lecture and four 2 day regional training sessions, by Aro Hospital and Lancashire faculty. Didactic and participatory methods included lectures, videos, role plays, discussions.	Knowledge tests pre- and post-course Caseloads of patients seen over the following 12 months	Post-training rates of accurate diagnosis by PHC workers significantly improved: 12.5% for psychosis(p=0.018), 12.5% for substance abuse(p=0.018), 30% for OSEC (p=0.001). Mean scores for appropriate intervention improved by 114% for psychosis (p=0.001), 109% for depression (p=0.001), 78% for substance abuse (p=0.001), 103% for epilepsy (p=0.001) and 92% for OSEC (p=0.001). 473 patients were treated in the following 12months (46% psychosis, 10% depression, 3% OSEC, 2.5% alcohol and substance abuse).
Bruni 2014 Ethiopia	Analysis of test scores pre and post- mhGAP-IG training.	General Health Workers 61	2 separate cycles of training: mhGAP Base Course: 5 day sequential training, followed by 6 months' supervision and mentorship, before the mhGAP Standard Course, which builds on the Base Course with revision and addition of further mhGAP- IG modules and building skills through participatory techniques.	Qualitative observations that: Attendance was closely related to per diem payments for attendance, which was low despite needing to cover accommodation and other expenses. Master trainers (experienced senior psychiatrists) were expected to cascade mhGAP training without formal preparation. A formal introduction to familiarize trainers with the mhGAP-IG and its training formula was recommended.	Statistically significant improvement in participants' knowledge scores post-training on the WHO standardised knowledge test from the mhGAP monitoring and evaluation toolkit. A table of 592 MNS cases detected and treated or referred following training, by region and diagnoses, was provided.
Budosan 2016 Philippines	Evaluation of an intervention to strengthen mental health service availability, accessibility and affordability in Eastern Visayas.	Community workers. Nonspecialized healthcare providers. 1038 + 290	10 months' mhGAP training (groups of 7-50+) and supervision on assessment and management of common mental health conditions and conditions specifically related to stress for non- specialized health workers. Existing training module for community workers reviewed and training materials piloted. Modules modified for midwives and health workers.	3-point Likert scale survey of training quality, duration, trainer, participation, confidence to assess and manage priority conditions. Acceptability was noted as government and health stakeholders were motivated to improve local mental health services.	155 of 159 (98%) PHC units, 21 of 24 District Hospitals (88%) and all 8 provincial hospitals had a doctor and nurse trained in mental health assessment and management. Variable confidence of participants in mental health assessment and management post-course. Higher confidence among community workers than non-specialized staff. Local services increased inpatient, pharmacy and

					referral pathway capacity following intervention.
El Chammay 2016 Lebanon and Syria	Descriptive account	Nurses, social workers, GPs at 50 PHC; Other staff at 30 PHC; Frontline staff 106 + staff at 30 PHC	 mhGAP-IG training of health workers in PHC. Psychological first aid training for staff in a further 30 centres. 4Ws (Who's doing What, Where, and until When) assessment to map existing resources. Training modules on suicide risk management for frontline healthcare staff. Supervision unit will support >100 PHC in Lebanon. 		Lebanon's mental health system is growing, despite challenges, due to: Momentum and interest created by the Syrian crisis. Policy to avoid parallel care systems. Collaboration between Ministry, UN, national and international NGOS. National consensus mental health strategy involving all stakeholders. High level Ministry support for mental health reform.
Ekore 2016 Nigeria	Quasi-experimental study. Volunteer trainees completed sociodemographic, Eysenck personality (short-form) questionnaires, focus group discussions and knowledge pre- test questionnaires. Received mental health peer counselling training before knowledge post-course test.	University student volunteers 20 45% male 55% female Mean age 20.2 years	2 day training (3 hours/day) course by clinical staff. Focus Group Discussions informed training, aimed at identification and referral of students having mental health problems, counselling and psychosocial support. Training covered epilepsy, psychosis, bipolar disorder, stress, alcohol and drugs, principles of care, communication, emergencies and peer counselling. Relaxation techniques were taught, record keeping, roles and responsibilities and an emphasis on commitment and altruism.		The mean knowledge pre- test score was 24/30 (±2.3) points while the mean knowledge post-test score was 27.5/30 (±1.2) points. Mean difference 3.5/30 (t=6.4, p=0.00).
Gureje 2015 Nigeria	Supervised mhGAP- IG cascade training model delivered over 18 months in 8 local government areas in Osun state. Training focused on detection and management of moderate to severe depression, psychosis, epilepsy and alcohol use disorders. Master Trainers (mental health specialists) trained Facilitators, who delivered training for front-line PHC workers. Initial training was supervised and mentored by Master Trainers. Refresher training was provided after 9 months.	PHC workers from 68 PHC. 198	3 planning workshops of key mental health stakeholders, including PHC workers and policy makers occurred, before a pilot training course to test methods including role plays. Facilitators were trained in all 9 modules of the mhGAP-IG, teaching skills, role play organisation and conduct. Training materials were contextualized and adapted by Master Trainers before giving them to Facilitators and delivering 2 day workshops. Facilitators attended de-briefing following initial, supervised training, to receive training observations and discuss areas for clarification. Midway refresher workshop reinforced knowledge and skills, with reference to clinical challenges and experiences.	 Clinical notes review for proper documentation. Non-intrusive supervisor observation of clinical assessments using the mhGAP-IG. WHO mhGAP monitoring and evaluation toolkit knowledge tests, contextualized for the Nigerian setting, were conducted midway and at the end of the project, alongside mhGAP-IG fidelity, patient flow and referral information. 	Markedly improved knowledge and skills of health workers (mean difference pre/post: -4.90, p<0.001). Significant increase in numbers identified and treated for MNS disorders (0 in 2011 versus 96 in 2013), and number of referrals (0 versus 45). Substantial retention of gained knowledge observed nine months after initial training but some knowledge loss with time, so the refresher training was needed (mean difference: 1.98, p<0.001)
Hamdani 2015 Pakistan	Pilot service for children with developmental disorders in a rural area.	Supervised 'champion' volunteers. Families of children with developmental disorders. 10 champions	Avatar-assisted Cascade Training (ACT): Standardised, intuitive tablet-based training and delivery tool developed. mhGAP-IG guidelines for developmental disorders incorporated into animated, interactive 'avatar' narratives about 3 children and families, divided into	Pre- and post-training knowledge, attitudes and practices questionnaire. WHODAS-Child at baseline and 3- monthly. Pre-post training child and family outcome evaluation: Strengths	Significant improvement in trained family member knowledge scores (n= 24) from 23.29 +/-3.22 to 27.17 +/- 2.11 (t = 8.36, P<.001). Significant decrease in WHO-DAS global disability score from baseline (56.89 +/- 22.02 to 50.57 +/-24.62, 95% CI

		70 families	training scenarios on psychoeducation, parent skills training, community participation, stigma, rights. Master's level psychologist trainer delivered 8 days' training for champions using ACT, to cascade the same 8 days' training to 5-7 families, each. Champions received monthly supervision and met families regularly after training.	and Difficulties questionnaire, inventory of stigmatising experiences, family empowerment scale, WHO-5 wellbeing index. Summary table of steps to replicate the innovation in other settings.	3.63 to 9.0; P<.001) in families receiving 6 month intervention. Reduction in parent- reported socioemotional difficulties scores in children (19.67 +/-5.24 to 13.40 +/- 4.76, 95% CI – 7.68 to 4.87; P<.001).
Hughes 2015 Sierra Leone	Descriptive account	Psychiatric nurses and community health workers 20 + 150	mhGAP-IG and PFA used for training. A range of providers and approaches acknowledged.	Positive feedback forms mentioned. More evaluation recommended.	Reflective comments that: 1) PFA seems to be an effective tool; 2) Just one support session can reduce staff anxiety and depression; 3) mhGAP-IG is useful for screening and management, and receives positive feedback from field work; 4) In Sierra Leone, psychosocial care, encompassing culturally appropriate local support and religion, are valued.
Humayun 2017 Pakistan	2 months' pre- training joint consultations with District Health Office. 6 months' monthly mental health 'camps' assessed 785 cases. Joint specialist and non-specialist staff provided advocacy and needs assessment in camps, in an apprenticeship model. mhGAP-IG adapted to local mental health needs and competence of PHC staff. mhGAP-IG interface simplified as too complex. Most training in Urdu due to limited English.	51 doctors working in: PHC (18); Hospitals (11); secondary care (14); administration (3); North Waziristan tribal area (5). 7 NGO psychosocial staff. 58	Three 2-day training workshops over 3 months, featuring: Large and small group discussions, individual exercises, seminars, role- play demonstrations. 3 psychiatrists adapted modules to local needs. Master trainer supervised guideline adaptation for use in the camps. 1 day training of trainers (ToT) workshop on rationale, content, method of mhGAP-IG. 2 external reviewers gave independent feedback on course, trainers and materials, before review by senior staff. Supervision: formal and informal case discussion, emphasising holistic assessment, psychosocial intervention, timely referral. Following camps, a local psychiatrist continued to supervise PHC staff informally and follow up difficult cases.	Feedback on: what was useful? What was not useful? Any suggestions? Summary of responses without description of collation.	Mean pre- and post-test knowledge scores were 15.43, 62% (p value 0.000, S.D. 4.05) and 19.48, 78% (p value 0.000, S.D. 3.13) respectively. mhGAP-IG was implemented to train PHC doctors in Pakistan. Lack of PHC resources hindered complete integration of mental health services into PHC. Pilot implementation of mhGAP-IG in PHC was initiated across five districts.
Lasisi 2017 Nigeria	Randomised controlled trial	Public and private primary school teachers in Kaduna. 84 (intervention), 75 (control)	Intervention: initial 3 hour training; 1.5 hour booster session 2 weeks later. Used mhGAP-IG module on behavioural disorders, focusing on ADHD, plus classroom management strategies for ADHD. Delivered using PowerPoint presentations, clinical vignettes, role plays, small group discussions and videos. Outcome measures: knowledge of ADHD, attitude towards ADHD,	Pre- and post- training knowledge and attitude scores.	Controlling for baseline scores, intervention group had significantly higher post-intervention scores on ADHD (SRAQ) and intervention knowledge (KBIQ) and less negative attitudes towards ADHD, compared with the control group. Intervention showed moderate to large effect sizes. Booster training was associated with a statistically significant

			knowledge of behavioural intervention. Control: waiting list.		increase in ADHD knowledge only.
Ryland 2015 India	Descriptive Account	Health Professionals	Training course using mhGAP-IG delivered by UK trainee psychiatrists who had attended a two-day 'train the trainer' course in the UK. Duration and training methods not described (conference abstract).		UK trainees gained experience of global mental health: cultural factors, stigma, differences in resources and health systems. Trainees developed competencies relevant to UK practice, by teaching and being assessed for workplace-based assessment.
Siriwardhana 2013 Sri Lanka	Protocol for a pilot RCT	PHC staff working with displaced and returning conflict- affected populations in Puttalam and Mannar districts. 86	Intervention arm: structured training based on mhGAP- IG depression, medically unexplained symptoms, alcohol abuse, and suicide modules. 5 full consecutive days' training by 2 psychiatrists. Control: waiting list. Initial 3 month monitoring from the date of recruitment pre-training. All patients with common mental disorders (CMD) reported to study coordinator. After training, both arms monitored again for 3 months. Intervention arm will use mhGAP-IG to diagnose, treat, and refer suspected CMD seen in routine PHC. Control arm will continue current practice. Both arms will report CMD diagnoses to coordinator. Consenting identified patients will be reassessed by the study psychiatrist, who will also assess them using mhGAP- IG.	A qualitative study exploring the attitudes, views, and perspectives of PCP on integrating mental health and primary care will be nested within the pilot study. An economic evaluation will be carried out by gathering service utilization information.	Protocol: Primary outcomes: rates of correct identification, adequate management based on set criteria, correct CMD referrals.
Siriwardhana 2016 Sri Lanka	Pilot and qualitative study with curtailed training duration and no pre or post- training monitoring and evaluation	PHC practitioners serving post- conflict populations, including internally displaced people and returnees.	Using mhGAP-IG depression, stress-related disorders, medically unexplained symptoms, substance misuse and suicide modules, a 24 hour training programme was held over 3 days. Modules were selected as relevant to the setting based on prior research into priority conditions, conflict- related context and participant backgrounds. WHO materials and videos were used. Training was delivered by a mhGAP-trained trainer and a local psychiatrist with clinical and research experience.	mhGAP-IG pre- and post-training knowledge tests. Feedback on training, materials and content gathered after each module. A small-scale qualitative evaluation highlighted experiences of conflict and displacement, discussed health needs of post-conflict populations and provided insight into mental health care and training needs in PHC	