



## Comprehensive mental health management by general practitioners in primary care

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### Abstract

**Introduction:** low supply of mental health professionals and low demand for psychiatric services contribute to a wide treatment gap

**Objective:** to compare patient outcomes after primary care mental health treatment by physicians or a clinical psychologist.

**Methods:** A pragmatic, partially randomized, cluster noninferiority trial was conducted in 28 primary care practices.

**Results:** there was a greater improvement in health among participants in the specialist arm (mean reduction in ERSN score of 2.86, SD 5.40).

**Conclusions:** Primary mental health care provided by the family physician was shown to be non-inferior to care provided by a clinical psychologist.

**Keywords:** mental health, general practitioners, primary care, psychology

Source: DeCS

### Resumen

**Introducción:** la baja oferta de profesionales de la salud mental y la baja demanda de servicios psiquiátricos contribuyen a la amplia brecha de tratamiento.

**Objetivo:** comparar los resultados de los pacientes después del tratamiento de salud mental de atención primaria por parte de médicos o un psicólogo clínico.

**Método:** Se realizó un ensayo de no inferioridad por grupos, pragmático, parcialmente aleatorizado, en 28 prácticas de atención primaria.

**Resultados:** hubo una mayor mejora en la salud entre los participantes del brazo de especialistas (reducción media en la puntuación ERSN de 2,86, DE 5,40).

**Conclusiones:** Se demostró que la atención primaria de salud mental proporcionada por el médico de cabecera no es inferior a la atención brindada por un psicólogo clínico.

**Palabras clave:** salud mental, médicos generales, atención primaria, psicología fuente: DeCS

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## Introduction

In many countries, the lack of mental health professionals and the high demand for psychiatric services due to stigma contribute to the wide treatment gap. While the median global treatment gap for psychosis is 32.2%, the treatment gap in low- and middle-income countries (LMICs) is estimated to be over 90%<sup>(1)</sup>. Experts suggested integrating mental health care into primary care to help close this gap. Geography and health are intrinsically linked, as reflected in the adjustment of health services to consider population density, demographic profile and accessibility<sup>(2,3)</sup>.

While the first WHO Programme of Action for the Mental Health Gap (MHG) Intervention Guide has been used by more than 80 countries and translated into more than 20 languages, few research studies directly addressed its use in LMICs, highlighting the pressing need for evidence<sup>(4)</sup>. Studies on barriers and facilitators to MHG use, adherence, and patient outcomes are particularly needed to inform local, regional, national, and global improvements. A recent WHO systematic review of MHG evidence from PIBM underscored the pressing need to understand the field's contextual challenges, detailed protocols, qualitative studies, and randomized controlled trials<sup>(5)</sup>.

An integrated care model in high-income countries is cost-effective, match patient preferences (especially older patients), lead to increased mental health care utilization, and results in increased treatment adherence and improved clinical outcomes<sup>(6,7)</sup>.

This study aims to compare patient outcomes following primary care mental health treatment by primary care physicians or a clinical psychologist in a primary care practice (PCP).

## Method

A two-arm, pragmatic, partially randomized, cluster noninferiority trial was conducted, where 14 primary care hospitals were assigned to receive the WHO MHG training and 14 hospitals with the co-location framework were assigned to the specialist arm in the city of Ambato. Participants (patients) were blinded to the other pathway, and outcome assessors were blinded to group assignment. This study was approved by the Universidad Regional Autónoma de Los Andes (UNIANDES).

In the specialist arm, clinical psychologists typically use a combination of primary and advanced psychosocial therapies to manage disorders. Because the trial was designed to reflect real-life practice, psychologists' choice of treatment was not recorded for research participants.

The clustered nature of the study allowed participating patients to be unaware of the existence of the alternative care pathway. Physicians were not blinded to treatment arm assignment. Outcome assessments at follow-up were conducted during home visits and were performed by a different evaluator blinded to treatment assignment.

Participants were adult primary care patients who visited any of the 28 PCPs during the recruitment period and were not currently receiving any psychosocial or pharmacological therapy for mental health problems that met the selection criteria.

In the treatment arm of the WHO MHG, participants' medical records and questionnaire booklets were given to the primary care physician who had received the complementary mental health training. Standard medical consultations were conducted, followed by a structured interview comprising the CIS-R and ERSN, located in the second half of the questionnaire booklet.

In the specialist arm, participants' medical records were passed to a general practitioner along with a request for referral to a psychologist. Next, standard medical consultations were conducted for any physical complaints before participants went to a psychology consulting room for a structured interview with the clinical psychologist. Only diagnosed participants were contacted six months later for a follow-up assessment. Finally, participants were reassessed using the full battery of questionnaires. At this point, no additional or replacement diagnoses were assigned to participants.

The screening questionnaire incorporates additional demographic questions on gender, education, employment and utilization of health services based on the Client Services Reception Inventory (CSRI)<sup>(8)</sup>.

The ERSN Health Outcome Scale of the Nation (ERSN)<sup>(9)</sup> is a 12-item scale for rating mental health service users on various mental and social



health aspects, each on a scale of 0 to 4. Ratings were made once all information was available through the clinical interview, and the clinician took less than 5 minutes to complete. The total ERSN score is a sum of the individual item scores; higher scores indicate greater mental health or social problems but do not indicate the severity of the disorder. The primary outcomes were changes from baseline to the 6-month follow-up assessment in participants' health and social functioning as measured by the ERSN.

The WHO Disability Evaluation Schedule (DES 2.0) is a generic health and disability assessment tool used across all conditions, including mental, neurological and addictive disorders. The DES 2.0 covers six domains of functioning: cognition; Mobility; Self-care; Getting along; Life activities; and participation<sup>(10)</sup>. This study used the 36-item self-administered version and took approximately 20 minutes to complete it independently. In addition, the complex scoring method based on item response theory was used, as recommended by the WHO.

The 3-level European Quality of Life Scale (EQ-5D-3L) is a standardized self-report measure of health-related quality of life. EQ-5D-3L ratings are commonly converted into composite utility scores using country-specific sets of values, which measure people's health-related preferences and weight each of the levels in each EQ-5D-3L dimension accordingly<sup>(11)</sup>.

Preliminary analyses compared the characteristics of participants with and without complete data at 6-month follow-up by treatment group. They were conducted for both primary and secondary outcomes. This analysis was used to understand the missing data mechanism and to determine appropriate methods for dealing with missing outcome data.

Analyses were performed using an intention-to-treat approach. The effect of service type on ERSN, EQ-5D-3L and CED 2.0 scores at six months was analyzed separately in randomized mixed-effects regression models. Database and

statistical processing of the data were performed and analyzed in SPSS 26 statistical software (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used for the results collection, presentation and interpretation.

## Results

Trial participants were recruited from adult primary care attendees at 27 participating PCPs (the 14 WHO MHG arms and the 13 specialist arms). During the recruitment period, 4944 adult primary care patients attended the general practice clinic at 27 participating clinics. After screening ( $n = 1484$  met the selection criteria) and in-depth psychiatric interview ( $n = 394$ ), 174 participants in the WHO MHG group and 151 in the specialist group received a formal diagnosis and were recruited to the study.

The original target sample size was 189 per treatment arm to account for possible clustering effects and an imbalance in the number of participants per group. After completion of the baseline measurements, the required sample size was recalculated with an intragroup correlation estimate of 0.025 for the primary outcome (ERSN) derived from the baseline data set.

At baseline, 174 participants in the WHO PASM group and 151 in the specialist group received a formal diagnosis of psychiatric disorders. The participants were invited to return for intervention and follow-up assessment six months after recruitment.

Table 1 compares the means of participants' dependent variables at baseline and follow-up and 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 pair of baseline and follow-up scores. There is no significant difference between the two treatment arms at baseline in clinical symptom severity (CIS-R total score), disability rating (CED 2.0) and quality of life (EQ-5D-3L). However, the difference in total ERSN score at baseline is significant  $t = -2.40$ ,  $df = 293$ ,  $p = 0.039$ .



Table 1. Medians of dependent variables at baseline and 6-month follow-up for participants who completed the trial.

|                      | Base          | tracking      | Test and difference sign        |
|----------------------|---------------|---------------|---------------------------------|
| CIS-R total score    |               |               |                                 |
| Total (n = 294)      | 10,97 (11,47) | 4.43 (5.49)   | t = 9.63, gl = 293, p = 0.000   |
| WHO PASM (n = 153)   | 10.08 (12.36) | 4,63 (5,73)   | t = 5.09, gl = 152, p = 0.000   |
| Specialist (n = 141) | 11,93 (10,37) | 4.21 (5.22)   | t = 9.62, gl = 140, p = 0.000   |
| ERSN total score     |               |               |                                 |
| Total (n = 287)      | 5.45 (5.13)   | 3,45 (4,49)   | t = 6.10, gl = 286, p = 0.000   |
| WHO PASM (n = 150)   | 4,64 (4,50)   | 3,40 (4,38)   | t = 2.66, gl = 149, p = 0.009   |
| Specialist (n = 137) | 6.34 (5.70)   | 3,50 (4,62)   | t = 6.26, gl = 136, p = 0.000   |
| WHO 2.0              |               |               |                                 |
| Total (n = 294)      | 23,62 (16,32) | 12,41 (13,99) | t = 11.56, gl = 293, p = 0.000  |
| WHO PASM (n = 153)   | 24,23 (16,89) | 12.10 (13.99) | t = 8.41, gl = 152, p = 0.000   |
| Specialist (n = 141) | 22,95 (15,71) | 12.77 (14.03) | t = 7.98, gl = 140, p = 0.000   |
| EQ-5D-3L             |               |               |                                 |
| Total (n = 295)      | 0,790 (0,132) | 0,829 (0,113) | t = -11.01, gl = 294, p = 0.000 |
| WHO PASM (n = 153)   | 0,781 (0,135) | 0,825 (0,112) | t = -9.32, gl = 152, p = 0.000  |
| Specialist (n = 141) | 0,800 (0,128) | 0,832 (0,115) | t = -6.31, gl = 140, p = 0.000  |

Source: statistical analysis,  $p \leq 0.05$

During the 6 months, 31 (9.5%) of the participants recruited at baseline declined further participation in the trial or were untraceable. Of these, 21 (67.7%) belonged to the WHO PASM arm, and 10 (32.3%) belonged to the specialist arm. Most dropouts were women (n = 23, 74.4%). More than half (n = 17, 54.8%) were married, and about half (n = 15, 48.4%) lived with their partners. More than half (n = 17, 54.8%) had less than high school education (low education), a higher percentage than those who completed the study.

Both groups experienced a similar improvement in social and health functioning (ERSN total score) at 6 months follow-up: the specialist vs. WHO MHG regression coefficient was -0.55 (95 % CI -1.69 to 0.58) with  $p = 0.341$ . The bootstrap procedure gave a 95 % CI of -1.46 to 0.35 with  $p$

= 0.232. Reanalysis using the one-sided 97.5 % CI showed that for  $\text{Beta} \leq 0$   $p = 0.829$ . Multiple imputation analyses (31 imputed observations at follow-up) supported the result: the regression coefficient of WHO MHG versus specialist was -0.55 (95 % CI -1.67 to 0.56) with a  $p = 0.333$ . The non-inferiority of primary mental health care provided by a primary care physician versus a co-located clinical psychologist in primary care was met for the primary outcome of the ERSN total score.

Among participants in the WHO MHG group (n = 173) and the specialist group (n = 151) who received follow-up, a large proportion of participants no longer met any diagnostic criteria according to CIS-R and were considered to be in remission (n = 152 and n = 134 respectively). There is no significant difference between the



two arms in remission rate, Chi-square = 0.164,  $df = 1$ ,  $p = 0.730$ .

In terms of treatment response among participants who had one or more intervention sessions, there was a greater improvement in health and social functioning among participants in the specialist arm (mean reduction in ERSN score of 2.86, SD 5.40) compared to participants in the WHO MHG arm (mean reduction in ERSN score of 1.11, SD 5.82). This difference is statistically significant ( $t = 2.26$ ,  $gl = 214$ ,  $p = 0.025$ ). However, there is no correlation between the number of follow-up therapy sessions and the magnitude of the reduction in ERSN score, Pearson's  $r = 0.04$ ,  $p = 0.457$ .

A higher proportion of participants returned for intervention sessions in the WHO MHG arm (82.4%) compared to the specialist arm (68.8%).

The mean ERSN score at baseline was significantly higher among participants in the specialist arm (mean 6.25, SD = 5.57) compared to the WHO MHG arm (mean 4.76, SD = 4.72), the adjusted mean difference of -1.49. There was little difference in utility scores between the two arms and during follow-up.

## Discussion

Primary mental health care provided by the primary care physician had a higher percentage of patients returning for intervention. The results show that family physicians were able to manage mental health problems in primary care and were probably the most preferred option, resulting in a significantly higher proportion of patients returning for follow-up treatments. On the other hand, follow-up appointments with a clinical psychologist cost health systems less and, as such, may be a more cost-effective option in the long run.

Supported by adequate sample size for the chosen methodology, our findings support the existing literature that the primary outcome, ERSN, was able to detect changes in the community for those with common mental disorders and those with higher ERSN scores at diagnosis<sup>(12,13)</sup>.

There is a possible selection effect for ERSN and clinical rating scores (CIS-R), as demonstrated by the significantly higher mean scores of participants in the specialist arm compared with mean scores in the WHO MHG arm. While the

reason for this is unclear, the primary care attendees who agree to see a clinical psychologist may be those with clearer impairment in health and social functioning, i.e., those who saw a need for specialist care. In addition, the existing literature reports that understanding one's challenges is a determining factor in help-seeking among people with mental health problems, which indicates that there is still a stigma associated with specialty mental health care<sup>(14)</sup>.

While the first WHO MHG Intervention Guide was used by more than 80 countries and translated into more than 20 languages, few research studies directly addressed the use of the MHG framework in LMICs, highlighting the pressing need for evidence<sup>(15)</sup>. A recent systematic review of WHO MHG evidence from low- and middle-income countries found 13 studies describing health worker training using the WHO MHG Intervention Guide but only nine studies describing the clinical implementation of the WHO PASM framework in low- and middle-income countries<sup>(5,21)</sup>.

Several studies were conducted in Kenya, including an evaluation of a WHO MHG mobile application for depression screening and a non-randomized longitudinal intervention study of adult patients seeking care for depression from rural public health workers or traditional health professionals trained in the WHO PASM framework<sup>(16)</sup>. Over three months, patients seeking care from traditional health workers significantly reduced depressive symptoms as measured by the Beck Depression Inventory.

On the other hand, the literature evaluating the efficacy of collaborative co-location of psychologists in primary care is even more limited, despite the abundance of articles extolling the virtues of a collaborative care model. Regarding the co-location of psychologists in primary care, one report shows that between 14% (South Dakota) and 50% (Rhode Island) of primary care physicians share the practice with a psychologist in US states<sup>(17)</sup>. The same report established a positive correlation between the state supply of psychologists and the percentage of co-location (Pearson's  $r = 0.58$ ). A meta-analysis has shown that the integrated care model improves patient outcomes, although it is unclear whether co-location is necessary or sufficient to improve outcomes<sup>(18,22)</sup>.

The fact that the participants were more willing to return to a primary care physician than to a clinical psychologist is in stark contrast to an earlier study of patient preferences for mental health providers conducted in England in conjunction with an efficacy trial<sup>(19)</sup>. The English study found that, when given a choice, primary care patients who met the criteria for depression preferred nondirective counseling or cognitive behavioral therapy with a psychologist over care from a general practitioner. Primary care patients were also reluctant to risk being randomly assigned to primary care physician care. Further in-depth, context-specific, cross-contextual research must be conducted to fully understand these differences<sup>(20)</sup>.

## Conclusions

Primary mental health care provided by the primary care physician was shown to be statistically non-inferior to care provided by a clinical psychologist located in primary care, reducing symptoms of the social and physical disability at six months.

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