

Data User Guide

Title:

PREMIUM twelve-month follow-up trial: Clinical Outcomes and Cost-effectiveness dataset from the Healthy Activity Program (HAP) RCT

Data Description:

The Program for Effective Mental Health Interventions in Under-Resourced Health Systems (PREMIUM) sought to develop and assess scalable psychological treatments that are culturally appropriate, affordable, and feasible for delivery by non-specialist health workers and apply these treatments to the two leading mental health disorders: moderately severe to severe depression (the Healthy Activity Program [HAP]) and harmful drinking (Counselling for Alcohol Problems [CAP]).

This data collection contains records of adult male/female Primary Health Centres (PHC) attenders (one patient per row) recruited in the trials site between October 28th 2013 and July 30th 2015, and followed-up for outcome assessments until September 30th 2016. It encompasses enrolment, treatment process (including therapy quality), cost-effectiveness, and clinical/other outcome data. Only variables relevant for the analysis of our twelve-month follow-up are presented.

Data Collection Methods:

The study collected three types of quantitative data - base-line, intervention process, and outcome assessments - at 3 and 12 months. Electronic tablets were used to capture the majority of this data, with the exception of part of the Client Service Receipt Inventory in the Outcome data. This data was uploaded as CSV (Comma Separated Values) files to the GCP-compliant STAR data collection platform (<http://opspl.com>) operated by the project. Some intervention process data e.g. therapy quality and clinical notes were collected on paper and manually entered into the STAR data collection platform or Microsoft Excel.

Data Preparation and Analysis:

Data cleaning was performed in three stages in accordance with strict protocols:

First, range and consistency checks (including verifying participant IDs) were performed on each data source by the data manager at the trial site each week. Issues and queries associated with the dataset were promptly addressed by the trial management team, and an audit trail of performed actions recorded.

Second, the data set was shared with the on-site trials manager (whilst maintaining blinding) who ran their own range, consistency, and missing value checks, and provided feedback to the data manager.

Finally, the cleaned dataset from the trials site was shared with the off-site trials statistician who would run further data cleaning checks, merge values held in separate databases into a single master database, and generate/transform variables for analysis using a STATA .do file.

All analysis (blinded) were conducted based on an *a priori* TSC/DSMC approved and published analysis protocol. Access to pre-locked data was only granted the data manager and independent statistician.

Additional Information:

The data presented here is limited to only key variables used for the twelve-month follow-up analysis.

Geographic regions:

Primary Health Centres in the north of Goa, a state on the west coast of India.

Key dates:

- Data capture took place between October 28th 2013 and September 30th 2016.
- Locked final 3-month outcome dataset sent to trial statistician on February 4th 2016
- Locked final 12-month outcome dataset sent to trial statistician and trial manager on October 16th 2016

Quality Controls:

Range and consistency checks were performed separately for each data source at weekly intervals. Queries identified were resolved promptly by the trial management team, and the database updated to maintain the audit trail.

Species:

Human research participants aged between 18 and 65 years.

Privacy:

- All interviews were conducted in private settings convenient to the participants.
- All data containing participants' personal identifiers have been delinked. In cases where it has been necessary to retain the link between identifiers and participant's data, security protocols have been applied. Paper data has been kept in secure cabinets and electronic data has been password protected at the trial site.

Ethics:

Ethics approval to conduct the trial was obtained from the Institutional Review Boards at the London School of Hygiene and Tropical Medicine, Sangath (the implementing institution in India), and the Indian Council of Medical Research.

Keywords:

Twelve-month follow-up, general adult depression, economic outcomes, counselling, lay counsellors, Goa, India, RCT.

Language of written material:

English.

Project title:

Sustained effectiveness and cost-effectiveness of the Healthy Activity Program, a brief psychological treatment for depression delivered by lay counsellors in primary care: twelve-month follow-up of a randomised controlled trial.

Funder/Sponsor:

Funder: Wellcome Trust, UK

Sponsor: London School of Hygiene and Tropical Medicine, UK.

Grant Number:

091834

Data Creators:

Forename	Surname	Faculty / Dept	Institution	Role
Vikram	Patel	Department of Global Health and Social Medicine	Harvard Medical School, Boston, USA	Contact Person
Benedict	Weobong	Faculty of Epidemiology and Population Health	London School of Hygiene and Tropical Medicine	Data Creator/Project Manager
Bhargav	Bhat	Data	Sangath, India	Data Creator/Data Manager
David	McDaid	Personal Social Services Research Unit	London School of Economics and Political Science	Data Creator/Researcher
Helen	Weiss	Faculty of Epidemiology and Population Health.	London School of Hygiene and Tropical Medicine	Data Creator/Trials Statistician

File Description:

Filename	Description	Access status	Licence
PREMIUM_HAP_Econ_dataset_3_and_12_months.dta	Dataset containing key variables used for the main effectiveness analysis. This includes: baseline, 3-month outcome, 12-month clinical outcomes and other outcomes variables. This also includes variables used for our mediation analysis, treatment delivery, and serious adverse events.	Request access	Data Sharing Agreement
PREMIUM_Repeated_Measures_Mediation_Long.dta	This 'long' format data set contains key variables used for the main repeated measures analysis, mediation analysis, and generation of line graphs.	Request access	Data Sharing Agreement
PREMIUM_HAP_Econ_dataset_3_and_12_months.dta	Data set contains key variables used for the main cost-effectiveness analysis. This includes: 3 and 12 month intervention health service use costs, out of pocket costs and productivity losses, as well as clinical outcomes used including Quality Adjusted Life Years scores.	Request access	Data Sharing Agreement
Data collection tools			
Beck_Depression_Inventory.pdf	A 21-item questionnaire assessment of depressive symptoms assessed on a scale of 0 to 3. It measures depression severity based on symptom scores.	Open	CC-BY
Client_Service_Receipt_Inventory_PtA.pdf	Questionnaire used to collect information about the utilisation and costs of health care and lost productivity (including that of care-givers).	Open	CC-BY
Client_Service_Receipt_Inventory_PtB.pdf	Part B of the CSRI was designed for the purposes of the PREMIUM trials to collect data on costs of medication/investigations	Open	CC-BY
PHQ9_Screening_Questionnaire.pdf	A short 9-item depression assessment tool that is able to detect and provide probable diagnosis of depression as well as a symptom severity score.	Open	CC-BY
PREMIUM_Abbreviated_Activation_Scale.pdf	PREMIUM abbreviated activation scale consists of 5 items that measure activation and reinforcement.	Open	CC-BY
PREMIUM_Patient_Intake_Form.pdf	A form designed to collect baseline data.	Open	CC-BY
PREMIUM_HAP_Therapy_Quality_form.pdf	A measure designed to assess therapy quality.	Open	CC-BY
WHO_Disability_Assessment_Schedule.pdf	A 12-item questionnaire for measuring functional impairment over the previous 30 days. In addition, two items assess number of days the person was unable to work in the previous 30 days.	Open	CC-BY
Documentation			
Data_codebook.txt	Twelve month follow-up data codebook organized under: variable name, variable description, value label for each variable, source of variable, and remarks/suggested variable transformation.	Open	CC-BY
PREMIUM_HAP_InfoSheet_ConsentForm.pdf	Patient information sheet ("What You Need To Know About The Study Of Counselling In Primary Care") and consent form used by study – English language	Open	CC-BY
PREMIUMcodebook_twelve-monthFU_HAP_CAP.docx	Codebook for dataset	Open	CC-BY