

Title:

PREMIUM twelve-month follow-up trial: Clinical Outcomes and Cost-effectiveness dataset from the Counselling for Alcohol Problems (CAP) 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]).

The data collection contains records of adult male Primary Health Centres (PHC) attenders (one patient per row) recruited in the trials site between 28th October 2013 and the 30th July 2015, and followed-up for outcome assessments until 30th September 2016. It encompasses enrolment, treatment process (including therapy quality), clinical/other outcome data, and cost-effectiveness 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 Analysis and Preparation

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.

Data Preservation

The following actions were performed to improve data access:

- 'PREMIUM_CAP_Information_Sheet.pdf' re-exported to PDF 1.4 to fix SymbolMT font issue
- STATA DTA files were exported to CSV and associated documentation stored separately

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 spanned 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 at weekly intervals separately for each data source. Queries identified were resolved promptly by the trial management team, and the database updated, maintaining 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

Harmful drinking, Counselling, Primary Care, Lay counsellors, Goa, India, RCT, Twelve-month follow-up, Alcohol

Language of written material

English.

Project title

Sustained effectiveness and cost-effectiveness of Counselling for Alcohol Problems, a brief psychological treatment for harmful drinking 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, United States of America	Data creator/Contact Person
Abhijit	Nadkarni	Addictions Research Group	Sangath, India	Data Creator/Clinical Lead
Bhargav	Bhat	Data	Sangath, India	Data Creator/Data Manager
David	McDaid	Personal Social Services Research Unit	London School of Economics and Political Science, London, United Kingdom	Data Creator/Researcher
Helen	Weiss	Faculty of Epidemiology and Population Health.	London School of Hygiene and Tropical Medicine, London, United Kingdom	Data Creator/Trials Statistician

Data User Guide

Associated Roles:

Forename	Surname	Faculty / Dept	Institution	Role
Benedict	Weobong	Faculty of Epidemiology and Population Health.	London School of Hygiene and Tropical Medicine, London, United Kingdom	Data Creator/Project Manager

File Description

Filename	Description	Access status	Licence
Research Data			
PREMIUM_main_12month_followup_effectiveness_wide_CAP.dta	This 'wide' format data set contains key variables used for the main effectiveness analysis. This includes: baseline, 3-month outcome, and 12-month clinical outcomes and other outcomes variables. This also includes variables used for our mediation analysis, treatment delivery, and serious adverse events. Stored in STATA DTA and CSV format	Request access	Data Sharing Agreement
PREMIUM_repeatedmeasures_mediation_long_CAP.dta	This 'long' format data set contains key variables used for the main repeated measures analysis, mediation analysis, and generation of line graphs. Stored in STATA DTA and CSV format	Request access	Data Sharing Agreement
PREMIUM_CAP_Econ_3_and_12_months_cc_dollars.sav	Data set contains key variables used for the main cost-effectiveness analysis. This includes: baseline, 3-month clinical/non-clinical outcomes such as Quality Adjusted Life Years score, and 12-month clinical/non-clinical outcomes. Stored in SPSS format	Request access	Data Sharing Agreement
Data collection tools			
PREMIUM_CAP_AUDIT.pdf	A 10-item screening tool to identify possible alcohol use disorders.	Open	Creative Commons Attribution (CC-BY)
PREMIUM_CAP_Problem_Inventory.pdf	A 15-item test that measures physical, social, intrapersonal, impulsive, and interpersonal consequences of alcohol consumption.	Open	Creative Commons Attribution (CC-BY)
Client_Service_Receipt_Inventory_PtA.pdf	The Client Service Receipt Inventory is a questionnaire used to collect information about the utilisation and costs of health care and lost productivity (including that of care-givers).	Open	Creative Commons Attribution (CC-BY)
Client_Service_Receipt_Inventory_PtB.pdf	Part B of the CSRI was designed to collect data on costs of medication and investigations	Open	Creative Commons Attribution (CC-BY)
PREMIUM_CAP_Screening_Questionnaire.pdf	A short 9-item depression assessment tool used to detect and provide probable diagnosis of depression and assign a symptom severity score.	Open	Creative Commons Attribution (CC-BY)

Data User Guide

PREMIUM_CAP_Patient_Intake_Form.pdf	A form designed to collect baseline data.	Open	Creative Commons Attribution (CC-BY)
PREMIUM_CAP_Disability_Assessment.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	Creative Commons Attribution (CC-BY)
PREMIUM_CAP_End_of_Treatment_Eval.pdf	The end of CAP treatment patient evaluation form was used to determine reason for discharge, overall patient response to treatment, and other factors.	Open	Creative Commons Attribution (CC-BY)
PREMIUM_CAP_Timeline_Followback.pdf	Timeline follow-back calendar	Open	Creative Commons Attribution (CC-BY)
Documentation			
PREMIUMcodebook_twelve-monthFU_HAP_CAP.docx	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	Creative Commons Attribution (CC-BY)
PREMIUM_HAP_Study_InformationSheet_consent_form.pdf	Information sheet (“What You Need To Know About The Study Of Counselling In Primary Care”) and patient consent form used by study – English language.	Open	Creative Commons Attribution (CC-BY)