

# Self-help plus (SH+) for South Sudanese refugees in Uganda

<b>Submission date</b> 13/03/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/04/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/09/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Refugees are at risk of psychological distress and a range of mental disorders. The aim of this study is to test a new guided self-help intervention with South Sudanese refugee women in northern Uganda. The guided self-help intervention is designed to reduce high psychological distress in hard to access humanitarian populations.

### Who can participate?

Women aged 18 or older who speak Juba Arabic, reside in the Rhino Camp refugee settlement area in the West Nile region in northern Uganda, with high psychological distress

### What does the study involve?

Participating villages in the Rhino Camp refugee resettlement area are randomly allocated into two groups. Women in one group are invited to participate in five sessions of two hours of audio-recorded guided self-help, with a picture-book that illustrates the audio material. Women in the other group receive enhanced usual care, consisting of a community health care worker describing psychological distress, its causes, and what one can do to decrease psychological distress; and access to existing mental health services provided at primary care facilities. Various indicators of mental health are measured before, immediately after, and 3 months after completion of the intervention.

### What are the possible benefits and risks of participating?

Likely benefits include reduced psychological distress and improved wellbeing. Discussion of difficult feelings may lead to temporary increases in psychological distress. In two small previous studies this risk has not been observed occurring.

### Where is the study run from?

Peter C. Alderman Foundation (Uganda)

### When is the study starting and how long is it expected to run for?

May 2016 to January 2018

Who is funding the study?

Enhancing Learning & Research for Humanitarian Assistance (ELRHA) Research for Health in Humanitarian Crises (R2HC)

Who is the main contact?

Dr Wietse Tol

## Contact information

### Type(s)

Scientific

### Contact name

Dr Wietse Tol

### ORCID ID

<http://orcid.org/0000-0003-2216-0526>

### Contact details

PCAF Uganda

Mawanda Road Plot #855

Kampala

Uganda

-

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SH+UG

## Study information

### Scientific Title

Guided self-help to reduce psychological distress in South Sudanese refugees in northern Uganda: a cluster randomized trial

### Study objectives

A guided self-help intervention will lead to larger reductions in psychological distress than enhanced usual care.

### Ethics approval required

Old ethics approval format

Ethics approval(s)

1. World Health Organization Ethics Review Committee, 12/07/2016, ref: RPC758
2. MildMay Uganda Research Ethics Committee, 04/10/2016, ref: #RECREf0307-2016

**Study design**

Cluster randomized trial

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

Community

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Psychological distress

**Interventions**

Villages in the Rhino Camp refugee resettlement area are randomised to the following two conditions. Interviewers will be masked for study condition of villages.

1. The intervention condition will consist of a guided self-help intervention called Self-Help Plus (SH+). SH+ consists of five two-hour audio-recorded sessions, facilitated by a lay facilitator, as well as a picture book that illustrates the material from the audio sessions. The intervention comprises 2-hour sessions, weekly, for 5 weeks.

2. The control condition will consist of enhanced usual care, consisting of psycho-education by trained community health workers and access to mental health care services delivered in nearby health centers.

Various indicators of mental health are measured before, immediately after, and 3 months after completion of the intervention.

**Intervention Type**

Other

**Primary outcome measure**

Psychological distress, assessed using the Kessler 6 (K6) at pre-treatment (included as screening measure), immediately post-treatment, and 3 months after completion of treatment

**Secondary outcome measures**

Secondary outcomes:

1. Functional impairment, measured using the World Health Organization Disability Assessment Schedule 2.0, 12-item, interviewer administered version
2. Self-defined psychosocial goals, measured using PSYCLOPS
3. Depression symptoms, measured using the Patient Health Questionnaire 9 (PHQ-9)

4. Post-traumatic stress disorder symptoms, measured using the Posttraumatic Checklist 6 Civilian Version (PCL-C6)
5. Subjective wellbeing, measured using the World Health Organization Wellbeing 5 (WHO-5)

**Mediator:**

1. Psychological flexibility, measured using the Acceptance and Action Questionnaire 2 (AAQ-2)

**Moderators:**

1. Exposure to potentially traumatic events, measured using the Harvard Trauma Questionnaire (HTQ), part A
2. (Additional) health service use, measured using survey questions designed for this study

**Other:**

1. Economic indicators (for cost-benefit analyses), measured using survey questions designed for this study
2. Treatment contamination check, measured using survey questions designed for this study

All outcomes, mediators, moderators and the economic indicators are assessed at pre-treatment, immediately post-treatment, and 3 months after completion of treatment by a masked team of interviewers not involved in service delivery. To ensure masking, the contamination measure will be administered by intervention facilitators, between the immediate post-treatment follow-up and the 3-month follow-up.

**Overall study start date**

20/05/2016

**Completion date**

16/01/2018

## **Eligibility**

**Key inclusion criteria**

1. Adults (18 years or older)
2. Women
3. Speaking Juba Arabic
4. Residing in the Rhino Camp refugee settlement area in the West Nile region in northern Uganda
5. Scoring above an established cut-off for psychological distress on the K6

**Participant type(s)**

Other

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

14 villages (7 in the intervention condition, 7 in enhanced usual care condition); screening in 2 groups of 20-25 participants in each village, for a total of 560-700 participants

**Total final enrolment**

694

**Key exclusion criteria**

1. Imminent risk of suicide
2. Observable signs of severe mental disorder

**Date of first enrolment**

20/03/2017

**Date of final enrolment**

13/04/2017

**Locations****Countries of recruitment**

Uganda

**Study participating centre**

**Peter C. Alderman Foundation Uganda**

Mawanda Road Plot#855

Kampala

Uganda

-

**Sponsor information****Organisation**

World Health Organization

**Sponsor details**

Avenue Appia 20

Geneva

Switzerland

1211

**Sponsor type**

Other

**Website**

<http://www.who.int/en/>

**Organisation**

Peter C. Alderman Foundation

**Sponsor details**

261 Madison Avenue  
9th Floor  
New York, NY  
United States of America  
10016

**Sponsor type**

Other

**Website**

<http://www.petercaldermanfoundation.org/>

**Organisation**

World Health Organization

**Sponsor details**

-  
-

Switzerland

-

**Sponsor type**

Government

**Website**

<http://www.who.int/countries/che/en/>

**ROR**

<https://ror.org/01f80g185>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

Enhancing Learning & Research for Humanitarian Assistance (ELRHA) Research for Health in Humanitarian Crises (R2HC)

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

## Intention to publish date

16/01/2019

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mark van Ommeren, World Health Organization or Wietse Tol, Peter C. Alderman Foundation.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	13/08/2018	01/08/2019	Yes	No
<a href="#">Results article</a>	results	01/02/2020	27/01/2020	Yes	No
<a href="#">Results article</a>	secondary analysis	12/09/2023	14/09/2023	Yes	No