

An efficacy study of sociotherapy group intervention in the Sexual Reproductive Health and Rights (SRHR) program in Burundi

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| Submission date 17/05/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 27/05/2016 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 05/10/2016 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Sexual Reproductive Health and Rights (SRHR) is a concept of human rights which applies to sexuality and reproduction. These rights extend to equal opportunities, rights and conditions of all people to have a safe and satisfying sexual life, and to be able to decide over their own bodies without coercion, violence or discrimination. In communities in post-conflict areas, such as Burundi, SRHR-related problems are particularly common. A huge amount of young girls are not married legally and are deprived of their rights to adequate family planning, as well as being victims of domestic violence. This study is looking at a sociotherapy program (a type of talking therapy which focuses on the environment and relationships with others) which has been designed to improve negative SRHR related consequences. The aim of this study is to evaluate whether of a sociotherapy program within a comprehensive SRHR program is an effective way of improving negative SRHR related consequences.

Who can participate?

Those aged 16 and over with SRHR-related problems.

What does the study involve?

Participating collines (villages) in Burundi are randomly allocated to one of two groups. Those in the first group attend a course of 15 group sessions of the sociotherapy programme over eight weeks. The sessions are run by trained facilitators and involve group discussions, role playing, and learning techniques to boost self-awareness and mutual understanding. Those in the second group continue as usual for the duration of the study, and are offered the sociotherapy programme after the study has been completed. At the start of the study and then again after eight and 15 weeks, participants in both groups have their mental health, social wellbeing and social skills measured using a series of questionnaires.

What are the possible benefits and risks of participating?

There are no direct benefits or risks involved with participating in this study.

Where is the study run from?

The study is run from Healthnet TPO Burundi and takes place in different collines (villages) in 7 communes spread over three provinces: Bujumbura Rural, Bubanza and Cibitoke (Burundi)

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

January 2016 to August 2016

Who is funding the study?

Dutch Embassy Burundi (Burundi)

Who is the main contact?

Professor Ivan Komproe

Contact information

Type(s)

Scientific

Contact name

Prof Ivan Komproe

Contact details

Healthnet TPO

Lizzy Ansinghstraat 163

Amsterdam

Netherlands

1072 RG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A Naturalistic Cluster Randomized Trial to study the efficacy of socio therapy group intervention in the SRHR program in Burundi

Study objectives

The aim of this study is to establish the efficacy of the group interventions sociotherapy on negative SRHR related consequences of participants among the target population of the project in three provinces in Burundi. Specification of the domains of negative SRHR related consequences are:

1. Psychosocial, family and community functioning,
2. Physical health, well-being and general mental health and
- 3). Psychological and social processes and rebuilding social structures of local communities.

The two main hypotheses are:

1. The group interventions sociotherapy is effective to reduce physical and mental health complaints, distress and disability for SRHR related problems
2. The group interventions sociotherapy is effective to increase wellbeing and the individual and communal perspectives of (re)building social structures of communities

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee of the Lumière University in Bujumbura, 04/05/2016, ref: ULBU/Psy/03218/2016

Study design

Naturalistic 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 below to request a patient information sheet.

Health condition(s) or problem(s) studied

The negative consequences of violations of Sexual Reproductive Health and Rights (SRHR) on mental health, well-being and social functioning.

Interventions

The study will be conducted in different collines (villages) in 7 communes spread over three provinces: Bujumbura Rural, Bubanza and Cibitoke. To avoid contamination of the intervention 15 collines (villages) in these 7 communes are randomly allocated to the sociotherapy groups or control groups.

Intervention group: Participants attend a course of 15 group sessions of the Sociotherapy Intervention (ST) over a period of 8 weeks. These sessions are guided by trained facilitators and involve group discussions, role playing, practicing the Johari window, the square of autonomy and the four-circle model about culture in new environments technique, implementing insights about types of families, socialization, social systems, and social identity, listening and relaying

the message, games and their importance, fundamental needs, emotions, the way to act in a new environment, communicating by signs (without words) and on prejudices.

These 15 sessions intervention consist of 6 phases with their own objectives to reach:

1. Security/peace
2. Confidence/trust
3. Mutual care and assistance
4. Mutual respect
5. New norms
6. Discussing the experienced change by reflecting the past and present situation.

All these objectives cover the following themes:

1. Having a desire/thirst to care for each other
2. Equality among the participants
3. Democracy during the sessions
4. Responsibility for the group process
5. Full participation
6. A focus on here, now and the future
7. Learning by doing to obtain and maintain change.

Control group: Participants are placed on a waiting list for the duration of the study. After the study they will be offered the opportunity to undergo the sociotherapeutic intervention.

Participants in both groups are followed up after 8 and 15 weeks

Intervention Type

Primary outcome measure

1. Mental Health is measured using the five-item version of the Mental Health Inventory (MHI) at baseline, 8 and 15 weeks
2. Social Wellbeing is measured using the Subjective Wellbeing scale (SW-4) at baseline, 8 and 15 weeks
3. Social functioning is measured using the RAND SF-12 at baseline, 8 and 15 weeks

Secondary outcome measures

1. General Health complaints are measured using the SCL-90-R (items 1, 4, 12, 27, 42, 52, 56) at baseline, 8 and 15 weeks
2. Societal changes are measured at baseline, 8 and 15 weeks using:
 - 2.1. The Sense of community index
 - 2.2. The Sense of coherence scale (SOC-13)

Overall study start date

01/01/2016

Completion date

20/08/2016

Eligibility

Key inclusion criteria

1. Aged 16 years and older
2. Sexual Reproductive Health and Rights (SRHR) -related problems

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

Sociotherapeutic intervention will convene 15 groups of approximately 7 household couples per group (N=15) in 15 groups in selected collines (N=225 respondents) and takes place once a week for 15 consecutive weeks. The control group (under waiting list condition) will convene also 15 groups of 14 participants per group (N=15) in selected collines (N=225 respondents). Total for two Clusters N=450)

Key exclusion criteria

Those who require immediate medical treatment.

Date of first enrolment

25/03/2016

Date of final enrolment

29/07/2016

Locations**Countries of recruitment**

Burundi

Study participating centre**Healthnet TPO Burundi**

Avenue Muyinga N°21, Rohero I

Bujumbura

Burundi

BP 1110

Sponsor information**Organisation**

Dutch Embassy Burundi

Sponsor details

Immeuble Old East

Place de l'indépendance

Bujumbura
Burundi

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Sponsor type

Government

Website

<http://burundi.nlabassade.org/>

Funder(s)

Funder type

Government

Funder Name

Dutch Embassy Burundi

Results and Publications

Publication and dissemination plan

Planned publication in a peer reviewed journal

Intention to publish date

20/08/2017

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date