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Evaluation of an inquiry-based stress reduction programme to reduce self-stigma in persons living with HIV and AIDS

Submission date
12/09/2017

Recruitment status
No longer recruiting

Registration date
27/09/2017

Overall study status
Completed

Last Edited
14/02/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Self-stigma, which generally involves negative self-judgements resulting in shame, worthlessness and self-blame, can cause damaging emotional distress among people living with HIV and other chronic illnesses. It also can harm a person's self-agency, quality of life, adherence to treatment, and access to services. Despite the widespread prevalence of self-stigma in many countries, there are relatively few interventions to address it. The aim of this study is to examine the potential role of a programme incorporating “Inquiry-Based Stress Reduction (IBSR): The Work of Byron Katie” in helping people living with HIV to overcome self-stigma and associated mental states.

Who can participate?
Adults aged 18 or over, living with a positive HIV diagnosis for longer than 3 months, and able to speak English fluently enough to take part in group discussions

What does the study involve?
The participants attend a 12-week programme using Inquiry-based stress reduction (IBSR): The Work of Byron Katie. This consists of weekly 3-hour sessions conducted by two trained and certified IBSR facilitators, plus 15-45 minutes of individual or partner work carried out six days per week. Participants are taught to recognise and perform deep self-inquiry about stressful and self-stigmatising thoughts, particularly around issues relating to living with HIV. They are taught to appraise their thoughts using four key questions: 1) Is it true?; 2) Can I absolutely know that it is true?; 3) How do I react when I believe that thought?; and 4) Who would I be without the thought? The participants learn to become more aware of self-stigmatising thoughts as they occur, and to work through those thoughts systematically in order to better manage their emotional and psychological symptoms.

What are the possible benefits and risks of participating?
Possible benefits to participants are the reduction in self-stigma and associated negative mental

states. Due to the deep self-inquiry performed as part of the intervention, there is the risk that participants need to revisit painful memories and recount past traumas. Any potential mental harm arising from this is mitigated by the techniques used in the intervention.

Where is the study run from?
The intervention takes place at the CONNECT Zimbabwe Institute of Systemic Therapy in Harare, Zimbabwe, with research support from the Royal College of Surgeons in Ireland, in Dublin, Ireland, and Impact Research International in Harare, Zimbabwe, and Pretoria, South Africa.

When is the study starting and how long is it expected to run for?
February 2014 to August 2014

Who is funding the study?
Trocaire (Ireland)

Who is the main contact?
1. Dr Stephen Macdonald
2. Ms Nadine Ferris France

Contact information

Type(s)
Scientific

Contact name
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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IBSR-2013

Study information

Scientific Title
'We are the change' – an innovative community-based response to address self-stigma: a pilot study focusing on people living with HIV in Zimbabwe

Study objectives
A psychosocial intervention utilising techniques of Inquiry-Based Stress Reduction (IBSR): The Work of Byron Katie, could influence levels of self-stigma, and other associated mental states such as depression, among a group of people living with HIV.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Council of Zimbabwe, 24/10/2013, ref: MRCZ/A/1782

Study design
Single-centre uncontrolled pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Mental health: self-stigma, depression, and other mental states, among people living with HIV

Interventions
Intervention name: 12-week programme incorporating Inquiry-based stress reduction (IBSR): The Work of Byron Katie.

Randomisation: None - all participants received the intervention.

Dose: weekly 3-hour sessions conducted by two facilitators trained and certified in IBSR; plus 15-45 minutes of individual or partner work carried out six days per week.

Duration: 12 weeks.

Intervention description: IBSR is a tool which helps users to identify, manage, and overcome negative thoughts such as shame, guilt, and other self-stigmatising beliefs.

Administration of the intervention: The experimental group participated in a 12-week programme combining facilitator-led sessions and individual or partner work. The IBSR intervention is a guided form of self-inquiry, where users are taught to recognise and perform deep self-inquiry about stressful and self-stigmatising thoughts, particularly around issues relating to living with HIV. Users appraise their thoughts using four key questions: 1) Is it true?; 2) Can I absolutely know that it is true?; 3) How do I react when I believe that thought?; and 4) Who would I be without the thought? By going through this process, users become more aware of self-stigmatising thoughts as they occur, and are able to work through them systematically, in order to better manage their emotional and psychological symptoms. The programme followed a curriculum based on the detailed core beliefs and issues identified in a previous study which focused on the underlying causes of HIV-related self-stigma, conducted among a diverse group of PLHIV in Dublin, Ireland, results of which were published in the Swiss Medical Weekly journal in 2015 (Ferris France et al. “An unspoken world of unspoken things”: a study identifying and exploring core beliefs underlying self-stigma among people living with HIV and AIDS in Ireland. Swiss Med Wkly. 2015;145:w14113. doi:10.4414/smw.2015.14113).

Intervention Type
Behavioural

Primary outcome measure
1. HIV-related self-stigma, quantitatively measured using the Internalized AIDS-related Stigma Scale (IASS), a psychometric scale measuring six items reflecting self-defacing beliefs and negative perceptions of people living with HIV and AIDS. Focus group discussions and one-on-one interviews will also be used to capture more detail about changes arising due to the intervention. Timepoints: baseline, 1-monthfollow-up, 3-month follow-up
2. Self-reported psychological wellbeing, measured using the Ryff Scales of wellbeing. Focus group discussions and one-on-one interviews will also be used to capture more detail about changes arising due to the intervention. Timepoints: baseline, 1-month follow-up, 3-month follow-up
3. Depression, measured using the Center for Epidemiological Studies – Depression scale (CES-D). Timepoints: baseline, 1-month follow-up, 3-month follow-up
4. Quality of life, measured using the HIV/AIDS Targeted Quality of Life scale (HAT-QoL). Timepoints: baseline, 1 monthfollow-up, 3-month follow-up

Secondary outcome measures

Qualitative reporting by participants of changes to self-stigma and associated mental states following taking part in the intervention. This was measured using semi-structured focus group discussions and interviews at baseline, 1-monthfollow-up, and 3-month follow-up

Overall study start date
03/06/2013

Completion date
30/08/2014

Eligibility

Key inclusion criteria
1. Individuals living with a positive HIV diagnosis for longer than 3 months
2. Over 18 years of age
3. Able to speak English with sufficient fluency to take part in group discussions
4. Willing to provide informed consent and sign an informed consent form

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 participants

Key exclusion criteria
1. Individuals with unknown HIV status
2. Individuals diagnosed with HIV in the last three months
3. Individuals currently undergoing psychotherapy treatment

Date of first enrolment
28/10/2013

Date of final enrolment
21/02/2014

Locations

Countries of recruitment
Zimbabwe

Study participating centre
Connect Zimbabwe Institute of Systemic Therapy (CONNECT ZIST)
18149 Ganges Road
Ridgeview
Belvedere
Harare
Zimbabwe
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Sponsor information

Organisation
Royal College of Surgeons in Ireland Department of Epidemiology and Public Health Medicine

Sponsor details
Beaux Lane House
Mercer Street Lower
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Sponsor type
University/education

Website
http://rcsi.ie/

Organisation
Impact Research International

Sponsor details
10 Clara Road
Marlborough
Harare
Zimbabwe
Zimbabwe

Sponsor type
Research organisation

Organisation
Royal College of Surgeons in Ireland

Sponsor details

Sponsor type
Not defined

Website
http://www.rcsi.ie/

ROR
https://ror.org/01hxy9878

Funder(s)

Funder type
Charity

Funder Name
Trocaire

Results and Publications

Publication and dissemination plan
Results of 1-month and 3- month follow-ups were submitted for publication as a single academic article which the trialists aim to publish in Q4 2017. Further analysis of the data may yield information which allows a second article to be published.

Intention to publish date
31/10/2018

Individual participant data (IPD) sharing plan
Anonymised quantitative data from surveys of participants will be made available as supporting material to accompany publications. However, qualitative data is derived from confidential interviews and focus groups. In line with the personal nature of these discussions, and the terms of informed consent to which participants agreed, the full transcripts will not be made available. Illustrative verbatim quotes will included in published articles where necessary to support the findings of the analysis. Transcripts are held securely by the research team at CONNECT Zimbabwe Institute of Systemic Therapy, and will only be made available, with prior agreement, in the event that audit is necessary.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article	13/02/2019	14/02/2019	Yes	No