ISRCTN16484746 https://doi.org/10.1186/ISRCTN16484746

Improving bereavement outcomes in Zimbabwe

Submission date
07/11/2017

Recruitment status
No longer recruiting

Registration date
21/02/2018

Overall study status
Completed

Last Edited
24/07/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Despite a high burden of bereavement in most African countries due to HIV, cancer, other non-communicable diseases, high levels of suicide and sudden deaths, this is an under-researched field. Due to the complex and individual nature of grief, community members struggle to respond appropriately to bereaved community members. Moreover, processing grief often takes longer than communities are willing to accommodate. In the year 2000, Jennifer Hunt worked with Island Hospice and Healthcare to design the 9-cell bereavement tool with a focus on improving community member's capacity to support the bereaved. The tool explores current support (comments, condolences, behaviours), and assists participants to identify those that are helpful, and those that are not. The tool helps to raise awareness to what grief can feel like over time, how people express their grief depending on their gender, context, and culture, and how community plays a role in what is accepted or expected as bereavement manifests over time. Research feedback following use of the 9-cell tool in different countries indicated positive outcomes such as the bereaved feeling better understood and being able to talk easily about the deceased. Community-level bereavement interventions and strategies such as the 9-cell tool are much needed across Africa with its high mortality rates, associated largely with poverty and exacerbated by diseases such as HIV/AIDS, malaria and tuberculosis. This is in addition to the increasing incidence and prevalence of non-communicable diseases such as cancer and a range of sudden deaths. The aims of this study are therefore to assess the feasibility of using the 9-cell bereavement tool at the community level, and to assess the feasibility of testing it in a larger study.

Who can participate?
People aged 18 and over who have experienced the loss of a loved one in the past 6 months

What does the study involve?
Two neighborhoods in Chitungwiza are randomly allocated to either receive the 9-cell bereavement intervention at the start of the study or to receive the intervention towards the end of the study. All participants complete questionnaires assessing mental health, social support and levels of grief at the start of the study and after 3 and 6 months.

What are the possible benefits and risks of participating?
There is no guarantee or promise that participants will receive any benefit from the study. While it is believed that no harm can occur during this study, risks may include challenges in processing

grief, high emotional burden or distress. Jennifer Hunt and a trained social worker from Island Hospice and Healthcare will be available during the sessions to assist where needed as they will be administering the intervention and are trained in counseling and working with the bereaved and highly distressed individuals. In addition, the Principal Investigator Barbara Mutedzi is trained in basic care and counselling, and as this project is supported by Island Hospice and Healthcare, participants would be referred for further counselling and assistance throughout the intervention period and following the evaluation.

Where is the study run from?
Chitungwiza (Zimbabwe)

When is the study starting and how long is it expected to run for?
July 2017 to June 2018

Who is funding the study?
BuildCARE (Building Capacity, Access, Rights and Empowerment) (UK)

Who is the main contact?
Barbara Mutedzi

Contact information

Type(s)
Scientific

Contact name
Ms Barbara Mutedzi

Contact details
9 Bryden Road
Mt Pleasant
Harare
Zimbabwe
-

Additional identifiers

Protocol serial number
MRCZ/A/2230

Study information

Scientific Title
Improving bereavement outcomes in Zimbabwe: a feasibility cluster trial of the 9-cell bereavement tool

Study objectives
The literature has shown that community-level bereavement interventions and strategies such as the 9-cell tool are much needed across Africa with its high mortality rates, associated largely with poverty and exacerbated by diseases such as HIV/AIDS, malaria and tuberculosis. This is in

addition to the increasing incidence and prevalence of non-communicable diseases such as cancer and a range of sudden deaths.

The aim of this study is to: (a) assess the feasibility of implementing the 9-cell bereavement tool at community level and (b) to determine the feasibility of evaluating the intervention using a cluster randomized control trial design.

Feasibility questions and success criteria:
1. Can the trialists deliver the 9-cell bereavement intervention?
2. Will the processes of a randomized cluster trial be possible?
3. Will the trialists be able to recruit at least 75% of the suggested sample size within 3 weeks?
4. Will the trialists be able to retain at least 75% of the trial participants in the 9 months of the study?
5. Is the intervention delivered as intended and does process data suggest the planned effect is likely?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Council of Zimbabwe (MRCZ), re: MRCZ/A/2230 - approval pending

Study design
Cluster randomised trial

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
The 9-cell bereavement tool is a community-based tool, working with and educating families and communities to provide support afforded by bereavement counseling and community whose current structures are unable to reach all people. Through Jennifer Hunt's work, it is appreciated that grief is best expressed within and supported by family and community. The tool uses wisdom inherent in societies to support individuals and families in crisis. It is a highly personal experience yet played out within one's culture, which has been traditionally viewed as supportive and communal as opposed to individualized. It adds knowledge to individuals who interact with it, revealing processes that individuals go through with regard to grief.

The research location will be Chitungwiza in Zimbabwe. As the study will consist of both an intervention and a control group for comparative purposes, two neighborhoods within Chitungwiza have been selected; one as the intervention and the other as the control group. Two homogenous neighborhoods within Chitungwiza have been selected to allow for comparative analysis. The two communities selected within Chitungwiza are namely St Mary's and Seke Unit M. They are homogenous in terms of having the same socio-demographic characteristics and value systems.

It must be emphasized however, that though St Mary's and Seke are seemingly homogenous, participants will be from diverse backgrounds with respect to age, type of employment, types of bereavement they may have gone through, education, different experiences and religions. The 9-cell bereavement tool accommodates for this as it specifically targets and accommodates difference and uniqueness, and moves away from a concept of homogeneity within a seemingly homogenous group because of the different grief and bereavement processes that vary widely per individual.

Chitungwiza is densely populated with a large surface area, which greatly reduces contamination between the two selected intervention and control areas. St Mary's (one of the communities in Chitungwiza) is in the North-west section and Unit M of Seke (the second community selected fro the trial) is in the opposite end, i.e. in the South-East part of the map, further reducing chances of contamination.

Random allocation will be conducted by a Statistician at King's College London, who will use an electronic system to randomly allocate the area which would be the intervention and the area which would the control group. Both the researchers (except the Principal Investigator) and the data analyst will not be aware of which cluster will be the intervention group and which one will be the control group. This blinding reduces influence that researchers may have when collecting the quantitative data sets from the community clusters (Rajagopalan et al., 2013:4-5) and any influence that the data analyst will have when analyzing the same data sets. Each community however will be advised that they will receive an intervention at different stages of the study, i. e. one community would receive the intervention after baseline data has been collected and the other would receive the intervention toward the end of the study.

Quantitative research tools: the Shona Symptom Questionnaire (SSQ) measures mental health; the MOS Modified Social Support Survey (MSSS) measures social support and the Texas Revised Inventory of Grief (TRIG) measures levels of grief per individual. These instruments were chosen for the culturally specific adaptability, their wide usage by other researchers as well as their ease of understanding and therefore administration. The Shona Symptom Questionnaire is culturally adaptable within Zimbabwe for the fact that it was developed in Zimbabwe by Zimbabwean researchers and in the local language of Shona. The MSSS and the TRIG have both been used and adapted in different cultural settings.

All the tools are designed to be self-administered. However, trained surveyors will be present to assist respondents who may require further assistance beyond initial instructions provided at the beginning of each data collection period. Socio-demographic information including age, socio-economic status / current employment, ethnicity, education level and dates when they were bereaved, will be collected in conjunction with the quantitative instruments. The socio-demographic information will allow for cross-tabulation in the analysis, as we compare the relationships between the socio-demographic information and experiences of grief, bereavement and loss in the different stages of the evaluation. Completing the questionnaire is estimated to take less than an hour.

Participants will complete the same questionnaires to serve as Midline Data after 3 months post baseline data collection and at Endline after 3 months post midline. These intervals were chosen as ideal to constitute meaningful changes, if any, in awareness around grief and bereavement. Pre- and post-test calculations will be used to assess change in participants' levels of bereavement.

Analysis and written reports will be conducted and established at all three levels of baseline, midline and endline as a form of monitoring and evaluation process. Success of the study will be measured against the research questions and success criteria. Data collection from Intervention and Control groups will be performed separately at all times and within a week of each other (maximum). Whilst it is ideal for data collection to be performed on the same day, logistics and budgetary constraints may not allow for this to occur.

Qualitative research tools: semi-structured discussion guides with open ended questions will be used as a qualitative evaluation tool for their topical and interpretive characteristics, i.e. they seek out explanations of events and descriptions of processes; and they make sure that the people being interviewed are able to share their lived experiences without the constraints of structured tools.

A focus group discussion will ensue to understand the feasibility of finding 3 participants which the participants know of and whom have been bereaved in the past 6 months within their communities. At the end of midline data collection, a focus group discussion will also be organized with the interventionists where focus will be on the quality of their interactions with the beneficiaries and what changes they noticed in their beneficiaries from their interaction with them after the intervention. Questions will also focus on what worked and what didn't work, what challenges they faced, the support they need moving forward, how they used the intervention and when. At endline, another focus group discussion will be organized with them to identify how feasible it was to retain engagement with the bereaved in their communities throughout the duration of the study, as well as to reengage come of the relevant questions from the midline. Important information to find out at both midline and endline in the focus group discussions is how and if the intervention was delivered as intended. Respondents will be probed on how they delivered the intervention. A focus group discussion with the trial participants who received the intervention in the communities will be conducted to undertand their experience of the intervention.

Group discussions will be structured to take not more than 45 minutes. The researcher will ask and take notes as the participants' responses. All group discussions will be conducted in the vernacular (Shona and Ndebele) and translated into English before being analyzed. It is anticipated that the information that emanates from the qualitative data will both inform the effectiveness of the 9-cell tool as well as help to inform the development of a more specific scale to measure healthy bereavement. The focus group discussions will be recorded, with the participants permission and deleted once transcribed and analysed.

Intervention Type
Other

Primary outcome(s)
Measuring the effectiveness of the 9-cell bereavement tool by collecting baseline, midline (at 3 months) and endline data (6 months) of an intervention group (who receive the intervention at the beginning of the trial) and a control group (who receive the intervention at the end of the study). To measure results at baseline, midline and endline of each group (control and intervention) the following tools and their corresponding measures will be used:
1. Mental health, measured using the Shona Symptom Questionnaire (SSQ)
2. Social support, measured using the MOS Modified Social Support Survey (MSSS)
3. Levels of grief per individual, measured using the Texas Revised Inventory of Grief (TRIG)

Key secondary outcome(s))

1. The feasibility of finding 3 participants which the participants know of and whom have been bereaved in the past 6 months within their communities, assessed with a focus group discussion
2. The quality of the interventionists' interactions with the beneficiaries and what changes they noticed in their beneficiaries from their interaction with them after the intervention. Questions also focus on what worked and what didn't work, what challenges they faced, the support they need moving forward, how they used the intervention and when. Assessed with a focus group discussion at the end of midline data collection
3. The feasibility of retaining engagement with the bereaved in their communities throughout the duration of the study, assessed using a focus group discussion at endline
4. How and if the intervention was delivered as intended, assessed with focus group discussions at midline and endline
5. The trial participants' experience of the intervention, assessed with a focus group discussion

Completion date
30/06/2018

Eligibility

Key inclusion criteria
Previous research indicated that interventions were more effective when administered closer (though not too soon) to the time of death of the loved one (Jordan & Neimeyer 2003:765; Allumbaugh & Hoyt 1999 in Jordan & Neimeyer 2003). Additionally, research suggests that six (6) to 18 months is a suitable period for administering bereavement interventions inclusive of their follow up (Jordan & Neimeyer 2003:774.) According to Jenny Hunt, the developer of the 9-cell bereavement tool, the 6-month mark usually represents a time when social support often fades and the reality of the loss sets in.

Inclusion criteria for trial participants will therefore be:
1. Individuals in the community who have experienced the loss of a loved one in the past 6 months from the recruitment date (even where someone has been bereaved within a week of the study, by the time the study is finished it will be over 9 months, so they theoretically are still eligible as 6 to 18 months is a suitable period for administering interventions inclusive of their follow up as indicated above)
2. They will be selected to represent a cross-section of the whole adult community, defined as:
2.1. Being 18 years and above
2.2. Equally representative of both male and female where possible
2.3. Represent all ages above the age of majority, i.e. 18 years of age
2.4. Have the ability to either verbally consent or be able to consent in writing
2.5. Have the ability to attend and participate in the study, preferably for the duration

Inclusion criteria for interventionists:
1. Individuals in the community recruited by community leaders
2. 18 years and above
3. Representatiove of both male and female where possible
4. Have the ability to either verbally consent or be able to consent in writing
5. Have the ability to attend and participate in the study, preferable for the duration

Participant type(s)
Mixed

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
143

Key exclusion criteria
Exclusion criteria for trial participants:
1. Members of the community who have not reached the age of 18 (It is acknowledged that there is a growing need to address the grief and bereavement challenges that young people experience, with the large numbers of single and double orphaned children on the continent, however this is currently beyond the scope of this feasibility study)
2. Those who have not been bereaved in the past 6 months or over 18 months
3. Those unable to physically attend and participate in the study

Exclusion criteria for interventionists
1. Aged below 18
2. Physically unable to attend and participate in the study

Date of first enrolment
01/12/2017

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Zimbabwe

Study participating centre
Chitungwiza
Zimbabwe
-

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
BuildCARE (Building Capacity, Access, Rights and Empowerment) (UK)

Results and Publications

Individual participant data (IPD) sharing plan
The 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/07/2023	24/07/2023	Yes	No
Protocol article	protocol	10/05/2019	22/05/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		01/04/2021	13/08/2021	No	No