ISRCTN13038027 https://doi.org/10.1186/ISRCTN13038027

Development and piloting of an intervention to reduce alcohol use and improve family engagement among fathers in Kenya

Submission date
25/09/2019

Recruitment status
No longer recruiting

Registration date
07/10/2019

Overall study status
Completed

Last Edited
17/11/2023

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
Problem drinking is a pervasive global mental health problem. Harmful drinking impacts men at high rates with 7.6% of deaths per year attributable to alcohol and has negative psychosocial, behavioral, and physical consequences. Men's drinking also extends beyond men to impact their families with men's drinking closely tied to intimate partner violence and harsh treatment of children. The consequences for men and their families are often worsened in climates of poverty, a condition common in low- and middle-income countries such as Kenya. To try and address these intersecting risks of men's drinking and family consequences, a five-session intervention to reduce alcohol reduction and improve family engagement intervention for fathers with problem drinking in Kenya for delivery by counselors with no prior mental health experience was delivered. The aim of the study was to examine whether the treatment was able to reduce alcohol use and improved fathers' family engagement, such as time spent with family, among fathers experiencing problem drinking in Kenya. The researchers did this by examining a small group of fathers who received the treatment and asking their family (a spouse and child) questions about their behavior as well. They also aimed to explore the other family members' individual mental health; overall family functioning, including couple and father-child relationship quality; family violence; and indicators of treatment motivation. The study's overall goal was to provide a preliminary evaluation of the treatment's effectiveness to assess viability for a larger trial.

Who can participate?
Men living in Eldoret, Kenya who are responsible for the care of a child between the ages of 8 and 17, meet criteria for problematic drinking, have drank alcohol within the past 2 months, and who are willing to have a partner and child participate in answering questions. Men who meet criteria for alcohol dependence (i.e., may experience physical withdraws from reducing drinking) are not eligible for the study.

What does the study involve?
Fathers who are willing to, and can, participate will all receive the same treatment, but will begin treatment at different times. Fathers will meet with a counselor 5 times over 5 weeks for about

90 minutes. The counselor will ask the father to talk about the positive and negative things happening in his family and how drinking may affect the family. The counselor will try to help the father find ways to have peace and understanding in his family, to become a leader in his family, and to drink less if they want to by talking about things that are important to them and how they can take steps to do those things. For fathers, mothers, and one child who are interested and can participate, they will be asked to complete surveys and answer questions. Both before and after the fathers complete treatment, everyone might be asked to do some activities together with their family, such as a group project, discussing their hopes for their family, or discussing a small problem. Fathers will be asked questions about family, how they deal with problems, drinking behavior, how they feel, and answer interview questions about anything they might have done in the past to try to drink less. They will complete the survey questions up to four times before and after the program to understand how they are doing in the time leading up to counseling. Mothers and children will also be asked questions about the family, father's behavior, their feelings, and issues with drinking. They will answer questions 4-5 times before the father is in the program, each week during, and 4-5 times after. For all participants, no names will be put on anything and questions will be asked in private so the answers will be private even from other family members.

What are the possible benefits and risks of participating?
Fathers will receive a counseling program that it is hoped will improve how well the family understands each other and that helps fathers drink less. Mothers and children answering questions will help researchers understand whether the program for fathers is successful. This study will help researchers help develop programs for families in the future. It is possible that some activities or questions might bring up uncomfortable feelings. Participants may also make changes in their life that may have the unintended consequence of leading to conflict at home. If a participant does not want to participate in any discussions or activities they can stop at any time.

Where is the study run from?
The study is run in Eldoret, Kenya in collaboration with Moi Teaching and Referral Hospital (MTRH) and AMPATH (a consortium of a consortium of North American Schools in partnership with the Kenyan Ministry of Health in partnership with MTRH).

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

Who is funding the study?
Duke Global Health Institute and the Duke Graduate School (USA)

Who is the main contact?
Dr Ali Giusto
ali.giusto@duke.edu

Contact information

Type(s)
Scientific

Contact name
Dr Ali Giusto

ORCID ID
https://orcid.org/0000-0001-7153-0672

Contact details
90 West St. Apt 16k
New York
United States of America
10006
+1 (0)9546145393
Ali.giusto@duke.edu

Additional identifiers

Protocol serial number
3980499

Study information

Scientific Title
A brief alcohol reduction and family engagement intervention for fathers in a low-resource setting: results from a multiple-baseline study

Study objectives
Problem drinking is a critical global mental health problem that accounts for 9.6% of disability-adjusted life years worldwide (Whiteford et al., 2010). Men are especially impacted with 7.6% of deaths per year attributable to alcohol use (Grittner, Kuntsche, Graham, & Bloomfield, 2012). Men's alcohol-related consequences often extend beyond the individual with a cascade of impacts on their families with ties to negative child outcomes and dysfunctional family systems (Leonard & Eiden, 2007).

This study aimed to examine the initial impact of the brief intervention on fathers' alcohol use and drinking-related problems affecting the family. The researchers hypothesized during and after treatment amount of alcohol consumed and number of days drinking among participants would reduce. Alcohol use changes were examined in depth as the most proximal outcome, as it was hypothesized that alcohol reduction would likely be necessary for improvements in drinking-related family problems. The researchers hypothesized that after treatment, fathers and their family members would report improvements in drinking-related problem behavior (i.e., fighting with wife when drunk) and family involvement. The researchers further aimed to explore secondary outcomes of family member's individual mental health; overall family functioning, including couple and father-child relationship quality. They hypothesized that there might be minimal improvements in these outcomes post-treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 03/05/2017 Institutional Review Board at Duke University (2200 West Main Street, Durham, NC 27705; Tel: +1 (0)919 684 4769; Email: campusirb@duke.edu), IRB Protocol Number: C0058
2. Approved 17/03/2017, Institutional Research and Ethics Committee at Moi University (Moi

Teaching & Referral Hospital building, 2nd floor. Door No. 219, PO Box 3-30100 Eldoret, Kenya; Tel: +44 (0)787723677; Email: irecmtrh@gmail.com or contact@irec.or.ke), Ref: IREC/2013/230

Primary study design
Interventional

Study design
Non-concurrent multiple baseline single case series design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Problem drinking among men, specifically fathers

Interventions
A non-concurrent multiple baseline single case series design, replicated across participants (n=9), was used to examine alcohol use changes among nine fathers who screened positive for problem drinking and related family problems. The multiple baseline design allows us to examine within-subject change across conditions replicated across different individuals using a number of essentially “mini” ABA designs through repeated measures (Smith, 2012). The term “non-concurrent” refers to the baseline and treatment phases beginning at different times for each patient, which mirrors how treatment may typically unfold. In this study, participants’ enrollment positions were randomized to different baseline start dates; start dates were staggered by one week. There are several advantages to using this design. First, as this is the first attempt to examine the impact of a novel intervention, a larger trial would be premature. Second, such a design controls for time and allows a cause-and-effect association to be established between treatment and outcomes with participants serving as their control (Barlow & Nock, 2009). The researchers hypothesized that most fathers would not meet criteria for problem drinking based on amount of drinking after the intervention and show a decline in drinking during and after.

Participants’ enrollment positions were randomized to different baseline start dates, and start dates were staggered by one week. Assessors were blinded to the intervention. Further, 1 month prior to the 5-week treatment and one-month post-treatment assessments were given to participants and consented family member (one spouse and one child). This is a single-centre study.

All fathers/participants received a 5-session treatment (60-90 minutes) rooting in motivational interviewing (MI) and behavioral activation (BA). The implemented treatment was a brief, value-driven program to reduce alcohol use and improve family-directed behaviors among fathers engaging in problem drinking for delivery by lay-providers. Development for the Kenyan context was based on a multi-stepped process. It began with qualitative analysis to understand contextually-specific drivers of alcohol use and family disengagement among fathers. This was followed by a systematic review of alcohol use and family-related treatments, initial manualization, then collaborative development with a local team in Kenya, and a brief pilot. From the development process, MI and BA were identified as optimal treatment components, in addition to gender transformative strategies (GTS) that focuses on expanding conceptions of masculinity. These strategies were combined and integrated, and a family focus was emphasized throughout.

A manual guides the 5-session intervention. The intervention begins with MI strategies to encourage engagement and readiness to change, as well as a discussion of the treatment rationale to demonstrate the connection between events, feelings, urges, and drinking behavior. This rationale guides later discussions about the participant's drinking patterns. Remaining sessions consist of BA with MI integrated throughout. BA targets positive reinforcement to reduce drinking behaviors through the scheduling and completion of value-driven activities. Fathers are prompted to choose both a family-value and a self-value to guide activity scheduling. A self-focused value allows for the scheduling of other pleasurable non-drinking activities and/or coping activities, while family-focused values encourage behaviors with or related to the family. Additionally, early in treatment GTSs are included to expand traditional ideas about manhood to help clarify family-related values and to increase motivation to complete family activities. Lastly, refusal skills are included in sessions 3 and 4 to aide in the prevention of a common drinking trigger—peers. Although developed for use in Kenya, it is anchored in evidence based principles conducive to adaptation for other settings.

Intervention Type
Behavioural

Primary outcome(s)
1. Alcohol use and spending measured using the timeline followback every 4 weeks prior to treatment, during treatment, and every 4 weeks post-treatment
2. Problem drinking measured with the Alcohol Use Disorders Identification Test (AUDIT) at baseline to assess eligibility
3. Father's drinking-related problem behavior (all reporters) assessed with a locally-developed measure 1 month pre-treatment and 1-month post treatment. A few sub items were assessed 4 weeks prior to treatment, during treatment, and every 4 weeks post-treatment.
4. Missed family time (all reporters) assessed using a locally-developed measure 1 month pre-treatment and 1-month post treatment
5. Paternal involvement and instrumental support (all reporters) assessed with the involvement subscale of the Alabama Parenting Questionnaire (APQ)1 month pre-treatment and 1-month post treatment

Key secondary outcome(s)
1. Readiness to change measured with the Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES) 1 month pre-treatment and 1-month post treatment. A few sub items were assessed 4 weeks prior to treatment, during treatment, and every 4 weeks post-treatment
2. Men's willingness to engage in treatment assessed with a locally developed item 1 month pre-treatment and 1-month post treatment
3. Family functioning assessed with a locally-developed tool 1 month pre-treatment and 1-month post treatment
4. Household decision making assessed 1 month pre-treatment and 1-month post treatment
5. Couple relationship quality assessed with locally developed items and the Dyadic Adjustment scale 1 month pre-treatment and 1-month post treatment
6. Harsh marital interactions assessed with the Conflict Tactics Scale 1 month pre-treatment and 1-month post treatment
7. Father-child relationship quality assessed with locally-developed items and with the Parental Acceptance and Rejection Questionnaire 1 month pre-treatment and 1-month post treatment
8. Child maltreatment assessed with 15-items from the Discipline Interview 1 month pre-treatment and 1-month post treatment
9. Caregiver mental health assessed with the Patient Health Questionnaire 1 month pre-

treatment and 1-month post treatment
10. Child mental health assessed by child-report and caregiver-report using the 19-item Brief Problem Monitor 1 month pre-treatment and 1-month post treatment

Completion date
01/06/2018

Eligibility

Key inclusion criteria
1. Male caregiver (referred to as fathers) identified as responsible for the care of a child between the ages of 8 and 17 years of age
2. Problematic drinking indicated by a score of 8-20 on the Alcohol Use Disorder Identification Test (AUDIT; Babor et al., 2001)
3. Alcohol use within the past 2 months
4. Willingness to participate in study and sign a consent form
5. Willingness to have one child and the other primary caregiver of the child participate in study assessments
6. Willingness of other primary caregiver and child to consent to participate

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
9

Key exclusion criteria
1. Living in a home that brews alcohol
2. Has not had any alcohol in over two months
3. AUDIT score below 8
4. Alcohol dependence defined as having an AUDIT score above 20 and/or exhibiting visible symptoms of withdrawal or past history of hospitalization when attempting to reduce alcohol

Date of first enrolment
10/05/2017

Date of final enrolment
20/08/2017

Locations

Countries of recruitment
Kenya

Study participating centre
AMPATH/Moi Teaching and Referral Hospital
Nandi Road Kapsoya Ainabkoi
Eldoret
Kenya
NA

Sponsor information

Organisation
Duke University

ROR
https://ror.org/00py81415

Organisation
Moi University School Of Medicine/Moi Teaching and Referral Hospital

Funder(s)

Funder type
University/education

Funder Name
Duke Global Health Institute, Duke University

Alternative Name(s)
Duke Global Health Institute, Duke Global Health Institute - Duke University, DGHI

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Funder Name
Graduate School, Duke University

Alternative Name(s)
Duke University Graduate School

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/03/2022	07/03/2022	Yes	No
Results article	Qualitative results	01/12/2021	17/11/2023	Yes	No
Other publications	Feasibility study	01/09/2021	17/11/2023	Yes	No
Preprint results		23/03/2021	13/08/2021	No	No