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Pilot implementation of *Bukhali*: A preconception health trial in South Africa

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Abstract

Objectives: This article describes the learnings from the pilot phase of the Healthy Life Trajectories Initiative, a preconception health trial for 18- to 25-year-old women in Soweto, South Africa.

Methods: The study compares two arms focussed on either physical and mental health (intervention; delivered by community health workers – 'Health Helpers') or standard of care plus (control; standard access to healthcare plus additional telephonic input on 'life skills'; delivered by call centre assistants). These are collectively referred to as *Bukhali*. Data on the pilot implementation of the *Bukhali* trial (n = 1655) were collected from (1) weekly team meetings, (2) two focus groups (one with the intervention team Health Helpers, n = 7; one with intervention participants, n = 8) and one paired interview with control call centre assistants (n = 2), (3) notes from eight debrief sessions with Health Helpers and (4) quantitative trial monitoring data. Qualitative data were thematically analysed.

Results: The findings clustered within three themes: (1) challenges for young women in Soweto, (2) priorities for young women in Soweto and (3) implementation challenges and perceptions of the intervention. Challenges were mostly related to tough socioeconomic circumstances and less prioritisation of living a healthier life. The priorities of employment and educational opportunities reflected the socioeconomic challenges, where health was not recognised as priority. The main challenge to participation and compliance with the trial was that young women in Soweto generally wanted a tangible and preferably financial and immediate benefit. Community peer sessions, despite being recommended by young women as part of the intervention development, were not successful. Many women also moved between multiple households within Soweto, which flagged concerns for a cluster trial and risk of contamination.

Conclusion: Preconception health trials should consider socioeconomic challenges present in urban poor contexts. Learnings from the pilot phase significantly affected the design and implementation of the main *Bukhali* trial.

Keywords

Low- and middle-income country, intervention, women's health, preconception health, preconception care, implementation science

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Introduction

The importance of the preconception period is receiving greater recognition in global health.[1–3] However, the promotion of preconception health in low- and middle-income countries (LMICs) is lagging.[4] Obesity is a particular concern for preconception health, since children of mothers who are obese before they become pregnant have a 26 times greater risk of becoming obese.[5] In South Africa (SA), an LMIC, the Birth to Twenty Plus cohort showed that by early adulthood, 47.5% of girls were either overweight or obese,[6] and that if a girl was obese by age 5 years, she had a 42 times

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greater risk of being an obese adult.[7] Findings from the Soweto First 1000 Days cohort reported that 67% of women presenting at their first antenatal clinic visit were either overweight or obese.[8] Concerns about obesity also extend to childhood in SA whereby one in four girls age 2 to 14 years, and one in six boys in the same age group, were either overweight or obese.[9]

Given the public health distress around childhood obesity, the SA Medical Research Council, partnering with World Health Organization and the Canadian Institutes of Health Research, launched the Healthy Life Trajectories Initiative (HeLTI) in SA. This initiative aims to establish a programme of research to generate evidence that will inform national policy and decision making around preconception health as an intervention opportunity. This evidence focusses on optimising young women's physical and mental health in order to establish healthier trajectories for themselves and future offspring, and to offset health risks, such as obesity. This programme is also being implemented in Canada, China and India. In SA, the trial is called *Bukhali*, which means smart/powerful in isiZulu (commonly spoken language in Soweto), with the catchphrase of 'Living your best life'. The aim of this article is to describe the findings and learnings from the pilot implementation of the HeLTI trial in SA, including a description of intervention strategies and adaptations to the trial design.

Methods

Study setting

The HeLTI site in SA is Soweto, a predominantly low-income, peri-urban setting in Johannesburg with a population density of 6357 people per km^2 according to SA's most recent national census.[10] Although there is economic diversity in Soweto, poverty-related challenges are a reality, including unemployment and food insecurity,[11] and poor access to appropriate health services, especially for young people.[12] Preconception health promotion with young women in Soweto is imperative, since a third of them will have their first child by the time they are 19 years old.[13] Furthermore, there are multiple non-communicable disease risks for young women in Soweto – these include overweight and obesity,[7] poor diet,[14–16] high sedentary behaviour[17,18] and physical inactivity in late adolescence.[19] In addition, young women in Soweto face mental health challenges, such as anxiety and depression,[20] and HIV remains a complex issue for young people in Soweto,[12] with young women being particularly at risk of HIV infection.[21,22] Given the evidence for the relationship between insufficient sleep and the risk of obesity, sleep is a health behaviour that was included in *Bukhali* trial.[23,24]

Qualitative formative research for HeLTI in Soweto highlighted a number of challenges for young women. These include difficulties around making healthy choices due to an unsupportive environment,[25] the need for mental health support and various social constraints such as challenges relating to social pressure and socioeconomic circumstances. An example of this is the pressure to succeed in school, particularly if the young woman is the first in her family to finish school and enrol in tertiary education. Socioeconomic challenges include food insecurity, unemployment and difficulty finding working.[26] Young women's preferences for intervention were found to be mixed, but there was consistency in the preference for community health workers (CHWs) as the delivery agent.[26]

Following expert consultations and formative work, the design of the *Bukhali* trial was conceptualised as a cluster randomised trial within 30 randomly defined geographical areas in Soweto. The primary aim of the trial is to evaluate the effect of a four-phase intervention, starting preconception, on the index child's adiposity status at age 5 years as determined by fat mass index (fat mass/height)^2 derived from dual-energy X-ray absorptiometry. The two-arm randomised controlled trial (RCT) included a health component (intervention arm) and a standard of care plus component (control arm, standard access to healthcare plus additional input on 'life skills').

Trial protocol

Ethical approval for the trial was provided by the Human Research Ethics Committee (Medical) at the University of the Witwatersrand (Ref.: M1811111). Written informed consent is obtained from all participants. The trial is registered with the Pan African Clinical Trials Registry (https://pactr.samrc.ac.za; identifier: PACTR201903750173871). The trial is recruiting women age 18 to 25 years (n = 6800) from the Soweto Young Women's Survey.

The intervention arm was designed to be delivered by CHWs (26–40 years old) who would (1) dispense multiple-micronutrient supplements and resource material, (2) provide health feedback (body mass index (BMI), blood pressure, anaemia and lifestyle) and free services (HIV and pregnancy testing) through monthly individual sessions and (3) facilitate monthly peer sessions on Saturdays. The stakeholder group of young women from Soweto asked that CHWs be termed 'Health Helpers' for the intervention. Health Helpers were required to have completed secondary school and have some tertiary training but were not required to have had any formal training as a CHW. Health Helpers received training in Healthy Conversation Skills (HCS)[27] as part of the recruitment process. HCS refresher sessions are held approximately every 12 to 16 weeks, and Health Helper HCS are reviewed by trainers. Once employed, Health Helpers received training to deliver the intervention.

The format of the individual sessions for the intervention clusters is provided in Table 1. The intention of these sessions was to provide additional support for behaviour change using HCS. Intervention content and training materials were

Table 1. Individual session format for main intervention.

BP	
Systolic BP (mm Hg):	Diastolic BP (mm Hg):
Doctor told they have high BP? (Y/N)	Taking high BP medication? (Y/N)
○ Normal – Systolic <120 mm Hg and Diastolic <80 mm Hg	
○ Elevated – Systolic 120–139 mm Hg or Diastolic 80–89 mm Hg	
○ Hypertensive – Systolic ⩾140 mm Hg or Diastolic ⩾90 mm Hg (referral needed)	
BMI	
Height (cm):	Weight (kg):
BMI (kg/m^2):	○ Normal weight (<25)
○ Overweight (25–29.99)	○ Obese (>30)
HIV	
Tested for HIV? (Y/N)	
○ Knows status	○ Doesn't know status
Iron supplementation	
Takes vitamins/supplements? (Y/N)	Takes iron supplement? (Y/N)
Hb g/dL:	
○ Healthy iron level – Hb ⩾12 g/dL (optimise with micronutrient supplement 2× per week)	
○ Low iron level – Hb 7–11.9 g/dL (take micronutrient supplement daily)	
○ Very low iron level – Hb <7 g/dL (referral needed)	
Mental health	
PHQ-9 score – Depression (>10 high):	GAD-7 score – Anxiety (>10 high):
○ Mental health: good (⩽5)	○ Mental health: normal (>5 and <10)
○ Mental health: distress (⩾10)	
Physical activity	
Total vigorous physical activity per week:	Total moderate physical activity per week:
Total moderate vigorous physical activity per week:	
○ Participant is meeting the guidelines. Total MVPA ⩾2.5 h/week (150 min/week) or total vigorous physical activity ⩾1.25 h/week (75 min/week)	
○ Participant is not meeting guidelines. Total MVPA <2.5 h/week (150 min/week) and total vigorous physical activity <1.25 h/week (75 min/week)	
Sedentary behaviour	
Total number of hours sitting on a day:	
○ Participant is meeting the guidelines. Total sitting time is less than 8 h/day	
○ Participant is exceeding guidelines. Total sitting time is more than 8 h/day	
Sleep	
Usual number of hours sleeping at night:	
○ Participant is meeting the guidelines. Total sleep time is 7–9 h/night	
○ Participant is not meeting the guidelines. Total sleep time is >9 or <7 h/night	

BP: blood pressure; BMI: body mass index; PHQ-9: Patient Health Questionnaire, nine-item scale; GAD-7: Generalised Anxiety Disorder, seven-item scale; MVPA: moderate- to vigorous-intensity physical activity.

designed with input from content experts, a specialised health curriculum developer and a graphic designer. Social learning theory concepts of knowing, doing and becoming were used in the materials.[28] Materials included a facilitators' manual for Health Helpers and resource books for participants. The materials were designed for use in monthly peer sessions with approximately 15 women, facilitated by a Health Helper, over 18 months. Each peer session was intended to take place at a central community venue in each cluster. The details of these sessions are outlined in Table 2.

Table 2. *Bukhali* intervention session details.

Sessions	Topics covered	Take-home activities	Take-home messages
1. Welcome and HIV	Getting to know each other; ground rules for the group; HIV/AIDS risks, diagnosis, treatment	Reflect on group experiences; reflect on HIV status and lifestyle choices	Know your HIV status
2. Non-communicable diseases, body composition and body shape	NCDs and risk factors; BMI, overweight and obesity; body image	Reflect on NCD risk factors and family history	Healthy eating and physical activity
3. Carbohydrates, sugar, fast food and other nutrients	Nutrients and energy balance; refined carbohydrates and sugar; fast foods and snacks; portion sizes	Reflect on food choices; keep a food diary for a week	Making healthy choices about what I eat and drink
4. Sitting and fitness	Physical activity, fitness and sedentary behaviour and association with health; physical activity intensities and recommendations	Keep a physical activity and sitting diary	I can be physically fit
5. Sleep	Importance of sleep; healthy sleep and how much is needed	Reflect on sleep patterns	Good sleep is important for good health
6. Understanding emotion	Perceiving, identifying and naming emotions; self-awareness and social competence	Reflect on emotions	Knowing how I really feel inside helps me live my life well
7. Contraception and pregnancy preparedness	Types of contraceptives; pregnancy preparedness	Reflect on contraceptive choices and preparing for pregnancy one day	Make wise choices about contraception and pregnancy
8. Fitness, body composition and body shape	Physical activity, fitness and body composition; the importance of healthy body composition; practical tips for improving fitness	Reflect on any changes to physical activity and fitness, and feelings about body weight; revisit physical activity diary	Be active and fit
9. Screen time, sleep and sitting	Screen time, recommendations and risks of excessive screen time; sleep, light and screens	Revisit sleep diary; keep a screen time diary for a week	Choose face-to-face connection and sleep well
10. Carbohydrates, sugar and fast food and other nutrients	Recap of healthy eating principles, and sugar, fibre, reading food labels	Reflect on favourite foods and drinks	Eating well keeps me healthy
11. Eating a variety of foods	SA food-based dietary guidelines; micronutrients Increasing micronutrient intake; anaemia	Complete the 'sugar challenge'; revisit food diary; reflect on anaemia symptoms	Make healthy choices about my diet
12. Sexually transmitted infections and chronic diseases	Sexually transmitted infections; recap of NCDs; body weight and fertility	Reflect on safe sex practices; reflect on NCD risk factors	Protect myself against any kind of disease
13. Managing emotions	Recap on emotions; emotional triggers; self-care; stress	Reflect on emotional triggers	Be in better control of my emotions
14. Carbohydrates, sugar and fast food	Recap on sugar and fast foods; eating and emotions; healthy eating ideas; recap on portion sizes	Revisit food diary; reflect on healthy eating choices	Be aware of my emotions and make healthy choices about what I eat
15. Fitness	Recap on fitness; measuring fitness; fitness and NCDs	Revisit physical activity diary	Stay fit and healthy
16. Salt and high blood pressure	Recap on A-food based dietary guidelines; salt and high blood pressure; making food taste good without adding salt, sugar or fats; recap on reading food labels	Revisit food diary	Make healthy choices about the salt in my food
17. Healthy sleep habits	Sleep hygiene: environment, routines and the effects of diet and substances	Reflect on sleep hygiene	Have healthy sleep habits
18. Taking care of myself	Taking care of emotions; emotions, decision and behaviour links	Reflect on intervention topics and changes made to behaviours and values	I am going to live my best life

NCDs: non-communicable diseases; BMI: body mass index; SA: South Africa.

Peer sessions were structured to encourage group discussion and also had take-home activities. Health Helpers follow up on the take-home activities. Since these are self-monitoring tools for the participants' use as prompts for behaviour change (rather than research measures), the follow-up of these activities is not specifically monitored. The facilitator manual contained information about each of the health topics, and essential information was included in the participant resource book.

If intervention participants become pregnant during this 18-month period, Health Helpers would deliver four individual sessions using material developed specifically for pregnancy: *Bukhali Baby*. This included a facilitators' manual and resource book, which cover basic information about pregnancy, healthy eating and physical activity in pregnancy; preparing for delivery and baby; and pregnancy milestones. Participants would also receive a free sonography session and gestational diabetes screening. Individual support would continue post-delivery.

To partially control for special attention given to women in the intervention arm, the control arm had a dedicated call centre which contacted participants once a month and delivered a curriculum on 'life skills' (not directly relating to health) via telephone, SMS and email – the 'plus' component. This was in addition to standard access to healthcare (standard of care). Control participants also had access to free HIV and pregnancy testing at the research centre and were advised to contact their local health facility for any other health concerns.

Data collection

We piloted the intervention and control arms in six random community clusters (three intervention, three control) commencing in early 2019. Identification and recruitment of clusters will be described elsewhere. Briefly, an online search was performed using the Google search engine to locate the information of all churches in Soweto (used to differentiate communities). The latitude and longitude of the 104 churches identified and verified were then classified using k-means clustering in order to define 30 communities with a 1 km^2 radius each. We piloted the intervention and control arms in six of these community clusters (three intervention, three control) commencing in early 2019.

A mixed methods approach was used. Data on the implementation of the pilot phase of *Bukhali* trial were collected from (1) weekly team meetings (meeting notes, between March and June 2019), (2) two focus groups (one with the intervention team Health Helpers, n = 7; one with intervention participants, n = 8) and one paired interview with the control call centre assistants (n = 2), (3) notes from eight debrief sessions with Health Helpers and (4) quantitative trial monitoring data extracted from the project's REDCap database.[29]

All Health Helpers and call centre assistants were included in the sample and were requested to participate in the focus groups and interviews via email. One of the call centre staff was not able to attend the interview due to being ill on the day of the interview. Intervention participants were purposively selected and contacted telephonically to request their participation in a focus group. The only criterion for inclusion (other than being an intervention participant) was their willingness to participate in a focus group. Two intervention participants did not arrive for the focus group due to unforeseen conflicting commitments on the day of the focus group. No repeat interviews were conducted, and given that no substantially new information was presented in the focus group with intervention participants (i.e. data saturation was reached), no further focus groups with intervention participants were planned.

The focus groups and interviews were conducted by author C.E.D. (MA, PhD), a female senior researcher with 20 years of experience doing qualitative research. C.E.D. had a prior working relationship with Health Helpers and call centre assistants, who were explained the reasons for doing the research. Although C.E.D. is the researcher responsible for overseeing the Health Helpers and call centre assistants, we believe that her experience with and insights into the intervention and control components of HeLTI (which also included the development of all intervention control materials and training of teams) outweighed the risk of any negative influence imposed on the focus group and interview process. C.E.D. had no prior relationship with intervention participants, and apart from explaining the reasons for doing the focus groups, and that C.E.D. is a researcher on the HeLTI team, no other information about C.E.D. was shared with intervention participants. C.E.D. has extensive experience working in cross-cultural settings, and has therefore had experience in navigating the cultural and socioeconomic differences between herself and the participants.

Each focus group or interview was approximately 1 h in length and took place at the South African Medical Research Council/Wits Developmental Pathways for Health Research Unit at Chris Hani Baragwanath Hospital in Soweto. These were audio recorded, with participants' written consent, and were conducted primarily in English and transcribed verbatim (and translated into English if necessary). An individual also fluent in local vernacular languages was present for the focus groups and was able to translate where necessary. This individual along with the facilitator took notes during the focus groups and interviews. Transcripts were not returned to participants for comment and/or correction.

The discussion guide for Health Helpers and control team covered issues around recruitment (challenges, reasons for refusal, young women's priorities, solutions to boost recruitment), and their perceptions of the intervention materials and delivery method. For intervention participants, the discussion guide covered their perceptions of life as a young

woman in Soweto, their priorities, their perceptions of the intervention so far (including recruitment), their reasons for wanting to take part, their perceptions of others' reasons for not wanting to take part and their suggestions for recruitment. Given the pilot nature of this study, the discussion guides were not pilot tested.

Analysis

Data were thematically analysed (manually using Microsoft Word, by C.E.D.) using a largely deductive approach.[30] The discussion guide formed the basis of an initial thematic framework, and this was further developed to encompass three main themes: (1) challenges for young women in Soweto, (2) priorities for young women in Soweto and (3) implementation challenges and perceptions of the intervention . After the initial stage of familiarisation with the data, codes were generated based on these themes, allowing subthemes to be formed. The next step involved searching for themes and subthemes in the transcripts, and continuously reviewing and refining subthemes. Once coded sections of text were summarised for each theme and subtheme, illustrative quotes for each theme and subtheme were extracted. The results of the analyses were not checked with participants.

Results

Challenges for young women in Soweto

It is clear from the data collected that young women in Soweto face numerous challenges (illustrative quotes in Table 3), relating mostly to their socioeconomic circumstances, and poverty and unemployment in particular. Intervention participants spoke of having limited opportunities for education and employment, which were made more stressful if they had children to care for. Within the context of these challenges, intervention participants spoke about young women in Soweto as having an 'undisciplined' lifestyle, and some were described as 'lazy'.

Living a healthy life was described in all groups as difficult, particularly in relation to healthy eating and exercise opportunities. Intervention participants believed healthy food was expensive, inaccessible and often unappealing. Non-communicable diseases were acknowledged to be widespread, but these were considered the norm rather than something to be concerned about. Conversely, intervention participants perceived HIV/AIDS to still be a major issue.

Priorities for young women in Soweto

Not surprisingly, the priorities expressed by intervention participants were largely to do with employment and educational opportunities (illustrative quotes in Table 4). Health was not seen to be a priority by intervention participants, and this was also expressed by Health Helpers as part of their debrief sessions. However, views around certain health topics seemed to be mixed according to intervention participants. An example of this is pregnancy: some women are seen to prioritise their health when pregnant (for the sake of their baby), while others are willing to take risks during pregnancy (such as smoking or drinking alcohol) and were perhaps not informed about the consequences of these risks. These views reinforce the mind-set of 'living for the now' and not prioritising the future.

This was highly pervasive from the discussions and links to young women's agency regarding their ability to influence their future. For some intervention participants, they vocalised that this mind-set came from their parents as a result of living tough lives. However, other participants spoke about changing this mind-set and breaking the cycle of poverty, and had aspirations to change things in their lives in order to affect the next generation. These responses indicate that Soweto is a diverse community in economic transition, described by one intervention participant as a 'culture' that is difficult to change.

Implementation challenges and perceptions of the intervention

Illustrative quotes for this theme are provided in Table 5.

Incentives. There was a widespread view across the groups that participating in the trial (or any research) in Soweto must involve tangible benefits for young women. The most tangible benefit mentioned was money – the R150 (approximately US$10) that women receive to cover their transport costs when they come to the research centre in Soweto for surveys and assessments. The intervention was intended to be conducted in participants' homes and neighbourhoods; it was not believed to be necessary to provide transport reimbursement when transport would not be required. This, however, was not the view of study participants, and the R150 turned out to be the only tangible benefit that could be provided in exchange for participation, even when the empowerment aspects of the intervention were emphasised. Knowledge about health, awareness of one's own health status or an improvement in health status were not perceived to be a sufficient benefit for young women in Soweto. Participating in research for the improvement of their own health was not a widely held motivator.

Health awareness and testing. Participants acknowledged that receiving information about their own health was useful. They were concerned about HIV self-testing as it theoretically does not require pre- and post-test counselling, and the anticipated trauma of receiving a positive result was perceived as a barrier to uptake. However, participants acknowledged that even counselling does little to lessen the blow of knowing one is HIV positive. A further complication was the perception of weight loss being linked to being HIV positive, which presents challenges for a trial that is promoting healthy

Table 3. Challenges for young women in Soweto.

It's not easy, I can say it's, you know like a roller coaster if you know what I mean . . . especially after school. You face a lot of things. (Intervention participant)
There's a lot of things that can drag you down here. ('Refuser')
Majority of women in Soweto . . . they have a lot of problems in their lives. Number one, they are just focussed on where their next meal is going to come from, so if you come in and you tell them they must participate in the study and there are no tangible rewards like something that they can use or maybe like food or whatever, they don't want to participate in that. They are not interested, they are saying, you are saying okay its pills, it's going to help me yes, and right now I have grade 11, I want to further my studies, are you guys going to help me with that, no . . . if you are an elderly child in your family you need to provide for your siblings, they are hungry . . . and for your children as well. (Health Helper)
Okay lifestyle wise, we can talk about the way we conduct ourselves, the way we live our lives as young women . . . it's not disciplined . . . we just want to rule ourselves . . . whatever comes to mind now we want to do it, you understand. And most of the time is not even something positive . . . (Intervention participant)
They are just lazy . . . You go to, you make an appointment with them, they don't show up, next time you go near her street, she is home, she is not doing anything. (Health Helper)
Most of them during the day they are tired, its hangover, so they don't have time to be busy doing aerobics what-what. So, they want to sleep, at night they wake up and go to the club. (Intervention participant)
And other thing is money, when you don't have money, you will not have that access, healthy food, everything that you need . . . It's expensive . . . Plus we don't like cabbage, hey . . . I have eaten it my whole life, so when you think of cabbage, no. No ways. (Intervention participant)
Fruits, we don't like fruits, we eat Simba chips . . . I don't like the orange because it spills, and it is cold in winter you see. So, I can compromise with the apple and the pear, I would rather eat dried fruits. I can't have these ones that leaks water. (Intervention participant)
They will tell you that they love this, what is this, bunny chow. You are telling us about veggies, and we are used to bunny chow. So, it's difficult for them to get over the junk. (Health Helper)
There are people who . . . netball, soccer . . . but then we become like ignorant to that. You can only send your kids there, but you as a young woman you don't think for yourself that I have to go and attend also. (Intervention participant)
They [noncommunicable diseases] are normal to them. Because I had a participant, she said her mom had stroke, then I told her that you have to change your lifestyle so that you don't get to that stroke. So she said okay . . . you are telling me to buy an apple, to buy something like fruits and eat those fruits, I want to eat to be full. I don't want to eat just to nibble on something, no, I just want to eat to be full. (Health Helper)
I have seen a lot of people, when they test now okay, they become okay they take their treatment and all, and then they default. I have had friends, I have three of them, who defaulted like constantly and the in and out of hospital, in and out of hospital, at the end of the day what then happened is that they passed away. And it is not that they don't get educated, when you come to the clinic, you get counselling after being tested positive, isn't it, so I don't understand, I don't understand the mentality. (Intervention participant)
You see that one, they are not okay, 'cause you are going to go home with that thing [HIV self-test kit] and test, you don't have any counselling right around you, and you don't want your parents to know, anyone to know. Yes, you want to see first, you do your test, and then there you go, positive, you faint there, and you die right there. (Intervention participant)
You are slender, you are HIV, you are sick. They pass such remarks. (Intervention participant)
Even if you are telling them that your weight is too big . . . they will tell you that no, I look fine, I don't want to lose weight. I think again the weight thing goes around the perception that in the location, you lose weight, you are sick . . . because immediately I start losing weight, everybody now will be on my case, what is wrong, are you taking your meds? . . . really and truly people will never lose their weights. Unless you become this tough and say I am losing my weight, I don't care what they say. (Health Helper)

weight. With regard to the free pregnancy tests, Health Helpers reported that some participants stated that these were viewed with the same scepticism as HIV tests, while others liked the opportunity to test. Some participants reported to be more afraid of being pregnant than having HIV (and hence not wanting to take a pregnancy test), and yet did not

Table 4. Priorities for young women in Soweto.

We live for the now forgetting that there is tomorrow . . . We don't prioritise the future. (Intervention participant)
We don't think about health. As long as we eat, we sleep, you live, that is all. (Intervention participant)
It should be a priority to us but it's not. It should be but it's not honestly. There are some who are prioritising their health and all, but even if you, you, I think if even the, let me say the surroundings we are in, like you can say that you are trying to prioritise your health and all but then you are in Soweto, the kind of food they sell. (Intervention participant)
Okay you can stop drinking alcohol, you can stop smoking [when you are pregnant], but when the cravings are here, do you think you want to cook broccoli and cauliflower or *kota*. You want to eat chicken wings; you want pork chops and what-what. (Intervention participant)
I smoked with the first born so why should I stop smoking with this one, today he is all grown, is all well, so why complications now. (Intervention participant)
I don't want it to change the culture, but I want it [*Bukhali* intervention] to work hand in hand with culture . . . I don't want it to change who we are, we cannot change. (Intervention participant)
. . . you cannot expect a frustrated person to live a healthy life. Because if a woman is staying at home, with grade 11, no money to go back to school, no information on how to get then education so that I can change my life, then we don't expect that person to healthy. Because mentally, physically, emotionally that person is not healthy. (Health Helper)
The most common one [topic] that makes them listen and want to hear what you have to say is about the job, when you're talking about me sending you guys links to go out there and apply. That one does grab their attention. (Control team member)
. . . a part of Soweto is like developing . . . it's different . . . we are the ones that actually limit ourselves. I am not going to say our parents, I am not going to play the blame game . . . I think it is totally up to you . . . you consider the fact that if I can further my studies I can get a better paying job, then I can take care of my kids, you know what I mean . . . I can tell you where I am coming from people are developing, people are changing their lives. People are going to varsity, people are getting better paying jobs, people are driving the cars, people are living the life, so I think it's totally up to us. (Intervention participant)
I just want to create a name for myself and leave a footprint, just leave a bit of evidence to show that I was alive, yeah that is what I want, and that is what is important to me. And obviously taking care of my kids; that would come as a benefit of creating a name for myself. (Intervention participant)
. . . breaking yourself from poverty . . . people should never be poor anymore, we are breaking that, we are tired of poverty, you understand. And I think what is important to me, I want to have a lot of money, but I don't want to go to school. (Intervention participant)

seem to feel empowered to make their own choices about contraception use.

Cluster contamination. A critical finding was that, according to trial monitoring data, 23% of participants in the pilot study migrated across several households during the pilot intervention period, which was reported as a strategy to share resources across family–friends–partner households. In most cases, these households were outside of the cluster within which the women had initially been recruited. It was reported by Health Helpers that in many cases, family members did not know where the young women had moved to or when they were coming back, and did not seem particularly concerned about finding out where they were.

Education material and peer sessions. Despite the need for financial benefit, intervention participants felt that the materials were appropriate for young women in Soweto and found them to be helpful and educational. Health Helpers also indicated that the resource book provided a good starting point for conversations with young women. Although the peer sessions (originally intended to take place on Saturdays) proved not to be feasible for the majority of intervention participants, these sessions were appreciated by those participants who did attend. One of the reasons given by the Health Helpers for the peer sessions proving not to be feasible was the co-occurrence of other community activities taking place on Saturdays, such as social grant pay-out days and funerals. A reason given for funerals being prioritised was the fact that free food was provided. Even after providing refreshments and shifting to offer multiple sessions per day and multiple Saturdays per month in close proximity, the peer sessions were still poorly attended. It was the perceptions of the Health Helpers that poverty and the difficulty to prioritise peer sessions exacerbated the challenges experienced with intervention implementation.

Table 5. Implementation challenges and perceptions of the intervention.

[Why are women not interested?] . . . money. They won't do something without money. (Intervention participant)

They want money . . . I can't do anything for free. They're complaining about money. 'Why should I be part of it if you guys are not going to give me anything?' Though we are trying to emphasise . . . trying to give information that is going to empower you, they still want money. That's the main challenge we are having. (Control team member)

They wanted to find out if you come to me, are you going to give me the 150, and I say no, you don't need the 150 because the 150 was to reimburse your transport money, so if I come to you, I am going to bring everything that you need for something that we are going to cover for that day . . . you are not going to get 150. And they are like no. They expect to get 150 for every session. For the group, and for the one-on-ones . . . they want for every contact they have with you, they want money. (Health Helper)

But with research there is no direct benefits to you . . . when you are doing research you don't really get direct benefits that come straight to you. The benefit will definitely benefit later, other people later, maybe someone in your family will benefit but it never gets direct benefit to you. (Health Helper)

But they don't see education as a benefit; that is the problem . . . That is not good enough at some point, it is not enough, to say well you are going to learn this about your health. (Health Helper)

. . . our challenges is that they will say okay we are interested, and when you come back to them, they are not at home. They are not at home, we go back again we don't find them, they don't pick up our calls, they ignore us but initially they said they are interested . . . (Health Helper)

They go to their boyfriends, and those boyfriends, they provide money for them, so they go to their boyfriends majority of the time. So, you go their house, even their moms, they even beg us, if you find her, please call me be back, I just want to know if she is fine. (Health Helper)

. . . when we did them from the beginning, we were doing the calling, we get wrong numbers, you end up you know fighting with someone over the phone. (Health Helper)

Okay my reason was I think this is research right, so I'm at home doing nothing, so I think is best if I participate in something that will help others in the future and maybe I am going through something or she is going through something, something that will help, maybe your research will help others in the future. (Intervention participant)

You are learning something each and every day. And before you go to those groups you start question certain things by yourself, and then you start thinking that when I go there, I will ask this and this and this. (Intervention participant)

You see even now I am carrying it [*Bukhali* resource book], everywhere . . . Everywhere I go, I carry it in my bag, even when I change bags, I take it with. (Intervention participant)

They like the books because they say that at least some of the things they read, fill them and then when you talk to them then, yeah. (Health Helper)

And other things in English they sound fine, but when you translate it to our language, you sound rude . . . It's like this person is thinking, why is she being rude to me? So other things are fine in English but in African language they sound a bit rude sometimes. So, it depends again on the relation you have with this person. (Health Helper)

. . . some of us grow up where you don't just talk what is happening with you or you grew up not having someone to talk to in so much that you are not used in sharing your things, your personal things to anybody. And you will find that it is difficult if you see that this person is having a burden but she is not willing, because you can see she is not used . . . you can try as much as you can to ask the open discovery questions but you come out with nothing, nothing at all, they just don't want to talk . . . (Health Helper)

Some of these challenges that these women are facing, just listening to her is not enough. Yes, it's good that she is having someone that she can trust and tell but what are you going to do with all the things that I told you. Because if you tell somebody something that have been bugging you for a very long time, you haven't told anyone . . . like one of my participants told me she was raped when she was doing grade 7 and this and that and all the stories. Now she is working, she is not good at making friends . . . she has not told a lot of people, her mother knows, her family knows but sometimes that thing comes back, and she does not have anyone to talk to. You won't always be there when she needs that particular person to talk to, and when you are going home you ask yourself – I wonder how she is feeling today? Calling her you also don't know whether you are not pushing too much when I am checking up on her, but you just don't know what to do. (Health Helper)

Some of them will even tell you that I am telling you this so how will you solve it, so they want a solution from you. And then they think that maybe if you give them a solution, I am taking that and I am going to use it. So, it can be a trap sometimes. (Health Helper)

HCS. Health Helpers' impressions about the use of HCS was that these were sometimes difficult to implement in African languages that they used with participants. In particular, the HCS approach promotes the use of 'Open Discovery Questions' which start with 'what' or 'how', which comes across as 'rude' in some South African languages. The HCS approach supports individuals in finding their own solutions (as opposed to being told what to change). However, Health Helpers mentioned that some participants preferred just having solutions given to them, that participants differed greatly in their willingness to talk and some participants were not willing to engage at a level that would help them identify solutions for themselves. Related to this, setting goals for health behaviour change (a key component of the HCS approach) was not viewed as a priority, which aligns with the lack of prioritisation of health itself. Health Helpers also raised the question of whether listening to (and not necessarily counselling) participants was enough in a setting like Soweto given the contextual challenges mentioned earlier. They pointed out that many participants wanted to talk about other problems that did not necessarily directly relate to health.

Micronutrient supplement. The mobility of study participants within Soweto and the difficulty of meeting up with the participant made it difficult to physically give the supplements to participants, and so supplements were left with another household member if the participant was not home at the time. Some participants were sceptical about the supplements, expressing concerns about whether the supplements would cause them to become pregnant.

Control arm. The monthly telephonic contact was mostly well received, particularly since it was not demanding of participants' time, and was not perceived to be too frequent. Topics that dealt with economic challenges, such as job readiness, were appreciated by control participants. Given the prevalence of these young women's social challenges, call centre team members mentioned that it was difficult to stay within the scope of the topic for the month, and not discuss the other challenges that participants were facing.

Discussion

This article highlights the value of piloting complex interventions and presents preliminary findings from a novel preconception health trial in Soweto. This is a setting with numerous challenges for young women, which influence their priorities and willingness to participate in intervention activities. The findings of this pilot confirm the challenges mentioned in the formative research in this setting regarding healthy choices[25] and the need for social support.[26] The most striking finding was the difficulty in successfully administering peer sessions despite success in other settings and interventions.

There are limited preconception health trials in LMICs, and few reflect on the challenges around trial study design and implementation. Of those that are published, similar and context-specific challenges have been reported. These findings have implications for the implementation of preconception health interventions in LMICs. A preconception trial being implemented in Tajikistan, Bolivia and Palestine using mobile technology to reduce unintended pregnancies[31] found that short text messaging was the preferred method for communicating intervention content. A community-based lifestyle intervention with 18- to 59-year-old women in their homes in Malaysia also experienced potential contamination between intervention arms due to the community setting.[32] Another CHW-delivered trial in Malaysia has experienced similar challenges to HeLTI with scheduling intervention sessions and low interest in the pilot stage of their trial.[33] A preconception calcium supplementation for the prevention of preeclampsia implemented in SA, Zimbabwe and Argentina experienced significant difficulties and delays with recruitment due to inadequate medical records, redundant patient contact details and delayed pre-pregnancy hospital visits.[34]

Despite the low prioritisation of health by young women as part of the HeLTI trial, the health status of women in Soweto warrants intervention, especially given the overburdened health system in settings like Soweto. Future research on preconception health trials in LMICs should consider as part of the intervention development and piloting: (1) identify the best approach to position crucial health messages for young women and engage with them and their community, (2) education material is appreciated when health literacy levels are low, (3) carefully consider study design (cluster versus individual randomisation), (4) understand that even best practice from successful interventions may not always translate in all settings and (5) preconception health messages may need to be embedded in intervention content that primarily focusses on other salient issues for young women, such as job readiness, entrepreneurship skills and educational attainment.

Adaptations to the HeLTI study design

Based on the findings from this pilot phase, there have been numerous changes made to the trial. Recruitment is still happening at community level, but randomisation is at the individual level, rather than by cluster. The intervention group will no longer receive peer sessions but will have strengthened monthly face-to-face or telephonic contact with their Health Helper. Specific adaptations include the following: (1) A social messaging community campaign has also been launched as part of HeLTI in Soweto so as to address health literacy, issues around values and priorities of young women and sensitising the importance of preconception health through linkages with priorities of young women; (2) health awareness results are provided after randomisation following baseline assessments on the same day (immediate feedback

and commencement with either intervention or standard of care plus protocol); (3) all HIV testing (in person with Health Helper or self-testing) comes with pre-counselling and post-test counselling follow-up, with linkages to further support within the community and to health services; (4) transport costs are reimbursed for all research centre visits, and token incentives will be provided as the participant progresses to offset economic barriers and improve motivation (e.g. participants will also be able to request help with printing their resume to address the unemployment challenges mentioned); (5) the education material originally intended for peer sessions will be provided during the individual face-to-face sessions for the young women to work through the modules, and questions arising from this will be given time during the monthly follow-up sessions; (6) the HCS approach has been modified to allow time to build rapport before commencing, in so doing minimising the perception of rudeness, and increasing sensitivity relating to non-health-related goals while finding ways to weave in health prioritisation; and (7) a driver has been appointed to assist with the delivery of the micronutrient supplements to participants at their homes, and follow-up SMS supportive texts are sent to encourage compliance.

The location of this trial being limited to one particular setting in SA, the analysis of the data by one author and the small sample size could be perceived as limitations of this study. However, the contextual complexities of Soweto presented in this article suggest that this focussed approach allows the research team to become fully immersed in the development, implementation and evaluation of a contextually relevant intervention that has the potential to be scalable. The use of focus groups, a paired interview and debrief notes as data sources strengthens this study, in spite of the small sample size. Furthermore, this article represents the initial stage of evaluating the implementation of the *Bukhali* trial, which is ongoing and is informed by the UK Medical Research Council guidance on process evaluation.[35]

Conclusion

In conclusion, complex interventions in poor communities are challenging, and there is a need for greater process evaluation before and during a trial, and flexibility in study design allowing for adaptation to improve the approach as new information is attained. This combination of evaluation and adaptability may ensure greater acceptability, feasibility and impact on the primary and secondary outcomes of a trial.

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Ethical approval

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Informed consent

Written informed consent was obtained from all subjects before the study.

Trial registration

Pan African Clinical Trials Registry (https://pactr.samrc.ac.za; identifier: PACTR201903750173871).

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