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RESEARCH ARTICLE

Feasibility, acceptability, and potential effectiveness of a human-centered design-derived intervention to improve community health workers' contraception outreach in rural Malawi

[version 1]

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Abstract

Background

Health Surveillance Assistants (HSAs) in Malawi are critical to addressing contraceptive access challenges through rural outreach. Self-injectable contraception also holds promise. The human-centered design-derived Ndingathe intervention aims to improve contraception outreach services by addressing HSAs' workflow challenges and enhancing self-injection counseling through a mnemonic and peer support from experienced users ("EUs"). During a six-month pilot of Ndingathe in two rural districts, we evaluated its acceptability, feasibility, and potential effectiveness.

Methods

We conducted 60 pre- and post-surveys with HSAs, 450 surveys with outreach clinic clients, 40 interviews with clients, 20 interviews with HSAs, 4 interviews with health system stakeholders, and 20 outreach

clinic observations from September 2023-February 2024. Findings were triangulated to assess feasibility and acceptability and to explore potential effectiveness against Ndingathe's theory of action, based on the Contraceptive Agency Framework.

Results

Workflow components, including bicycle provision, lunch allowances, and work planning templates, were well-received by HSAs, and appear to have effectively increased outreach; the percentage of HSAs reporting the recommended 1-5 outreach clinics per week rose from 35% to 94%. HSAs' reported average role conflict and overload scores decreased (from 3.7 to 3.18 and 3.65 to 3.03, respectively, $p < 0.001$). Clients appreciated the option to attend clinics in the afternoon; observational data confirmed extended hours were utilized. Challenges included delays in lunch allowance payments that impacted HSA's morale and service delivery. The locally-derived self-injection mnemonic was well received by both HSAs and clients. Clients' self-reported fear of needles decreased after interacting with EUs ("very afraid" responses dropped from 49% to 3% among clients; $p < 0.05$). Clients who attended outreach clinics valued reassurance from EUs, especially during follow-up visits.

Conclusion

Ndingathe was feasible and acceptable and may improve contraceptive agency by improving service accessibility and reducing fear of self-injection. Ndingathe shows promise for improving rural contraception outreach services.

Keywords

self-injection, contraceptive services, community health worker, peer support, rural health

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Introduction

The ability to access contraception and decide what, if any, method to use is essential for personal autonomy and allows individuals to exercise their reproductive rights.^{1,2} Yet, access to contraceptives in rural areas of low- and middle-income countries (LMICs) is fraught with unique challenges related to inadequate healthcare infrastructure,³ inconsistent supply chains, and stigma related to contraceptive use that stems from religious and cultural beliefs and inequitable gender norms.⁴⁻⁶ In Malawi, over 80% of the population live in rural areas, making these challenges particularly salient.⁷

One promising approach to overcoming contraceptive access barriers in rural areas is through the utilization of community health workers (CHWs).⁸ In Malawi, CHWs, locally known as Health Surveillance Assistants (HSAs), play a crucial role in delivering healthcare services to rural communities.^{9,10} These workers are often people's first point of contact for health-related issues and are instrumental in promoting and providing contraceptive services, among many other primary care services. However, HSAs face challenges such as insufficient contraceptive counseling training, lack of resources to get to and from communities, and logistical difficulties, which hinder their effectiveness.¹¹

In addition to CHWs, emerging self-care technologies hold promise in empowering rural women to use contraception on their own terms. Research indicates that self-injectable depot medroxyprogesterone acetate (DMPA-SC) offers numerous benefits from clients' perspective, enhancing both accessibility and autonomy in contraceptive use. Studies, such as those conducted in Ethiopia, Uganda, Malawi, and Pakistan, reveal high satisfaction rates among women who choose this method.¹²⁻¹⁴ Self-injection (SI) is associated with higher continuation rates than provider-administered DMPA-SC, suggesting the method may live up to its potential to allow women greater control over their reproductive health.¹⁵ In Malawi, one of the first countries to scale-up provision of DMPA-SC for SI, HSAs are trained to deliver DMPA-SC for SI, yet rates of use remain low,¹⁶ particularly in rural areas.¹⁷ Recent calls for innovative SI programming highlight the need to not only ensure the availability of this contraceptive method option but to make sure women have support to overcome fears of injecting themselves and follow-up support for users who request it.^{18,19}

To help fill the gap in evidence-based models for improving contraceptive outreach services in rural areas, we developed the Ndingathe intervention through a participatory, human-centered design process in collaboration with community advisory boards.²⁰ Ndingathe aims to improve accessibility of contraception outreach services and enhance counseling and support for SI of DMPA-SC with the ultimate objective of improving women's agency related to contraception. The intervention is designed to improve agency through two mechanisms. First, Ndingathe increases service accessibility by addressing logistical barriers faced by HSAs that hinder their ability to conduct outreach to the most rural communities. Second, Ndingathe enhances SI counseling and support for women interested in SI through a locally-developed counseling mnemonic and by pairing HSAs with experienced users of SI who support women during outreach clinics and afterwards in their homes upon request.

In this study, we sought to evaluate the feasibility, acceptability, and potential effectiveness of Ndingathe to assess viability for a larger effectiveness trial. We conducted a 6-month pilot with an embedded mixed methods evaluation study from July to December 2023 in Ntchisi and Mulanje districts. Here we report on findings triangulated from surveys and interviews with key participants and recipients of the pilot, including clients, HSAs, and experienced users of SI.

Methods

Study design and setting

This cross-sectional, mixed methods pilot study was conducted in Ntchisi and Mulanje districts of Central and Southern Malawi, respectively. The Ndingathe intervention was piloted from June to December 2023 and follow-up study activities continued through February 2024. Ntchisi is predominantly rural, with the Chewa people being the largest ethnic group, while Mulanje is more densely populated and ethnically diverse with a blend of rural and semi-urban communities.²¹ Specific communities in each district were selected based on the geographical spread of the rural areas HSAs cover so that there would not be any overlap.

Description of the intervention

We developed Ndingathe through a collaborative, human-centered design approach whose objective was to develop an approach to improving HSAs' contraception outreach services, including for DMPA-SC self-injection. We report on the process of developing Ndingathe elsewhere.²⁰ Briefly, through research with HSAs and their clients, we identified key barriers and facilitators impacting contraceptive outreach services. We then organized participatory design workshops, bringing together public health researchers, Malawian health officials, HSAs, women, and adolescents. These workshops aimed to brainstorm and refine ideas, and develop and test prototypes of the ideas, ultimately in the final Ndingathe solution. During the design phase, research findings revealed that while clients generally trust and value HSAs, HSAs in

rural Malawi face significant challenges, such as limited transportation to rural areas and insufficient autonomy in managing their responsibilities.²⁰ Clients expressed a strong need for more timely contraceptive care and opportunities to learn from other women’s experiences, particularly from those familiar with self-injection of DMPA-SC. Guided by these insights, we developed a streamlined solution that 1) optimizes the HSA workflow and 2) strengthens SI support.

The HSA workflow component of Ndingathe consists of providing HSAs with a bike for transport and a lunch allowance so they could deliver services to hard-to-reach areas (geographically isolated) for the entire working hours expected by the Ministry of Health (MOH) (8 am-4 pm), during outreach clinics. Another workflow enhancement included training HSAs to use a biweekly work planning tool with support from a supervisor. The tool encourages HSAs to proactively plan more community outreach clinics in the rural areas. Under the enhanced SI provision component, each HSA enlists two locally-based women from the area they provide outreach out who have experience self-injecting to assist them at the outreach clinics. These women are referred to as experienced users or “EUs.” An EU’s role includes demonstrating the self-injection process, sharing their own experiences, and providing follow-up support to interested women (offering individual follow-up immediately after outreach and at 3 months). The SI component of the intervention also includes a locally-developed mnemonic for HSAs and EUs to teach women the critical steps in the self-injection process. The mnemonic was known as “Sakufima”, which translates to “Shake, Close, Insert, Squeeze” in the local Chichewa language.

The Ndingathe theory of action (Figure 1) is based on the Contraceptive Agency Framework and depicts the two main pathways by which we posit that the intervention will lead to improvements in women’s contraceptive agency and increase use of self-injection.²² First, Ndingathe is designed to improve service accessibility by improving HSAs’ workflow and the number of outreach clinics they can conduct in rural areas. Second, enhanced provision of DMPA-SC for SI is designed to lead to increases in clients’ self-efficacy and perceived control over contraceptive decision-making and self-efficacy to self-inject. It is important to note that Ndingathe does not aim to increase the percentage of women using SI by any specific percentage, in line with rights-based principles for contraception care.²³ Rather, because SI was an under-utilized technology when we developed Ndingathe, we hypothesized that the enhanced SI service provision—important in its own right to ensure women are equipped with the knowledge and support for SI should they choose that option—would also likely lead to increases in use. HSA and EU training as part of Ndingathe stresses the centrality of a focus on agency, regardless of what methods a person selects during an outreach clinic, and equips EUs to neutrally share their own personal experiences with SI without directing women to choose the method if it does not match their preferences.

Evaluation design

In total, 60 HSAs (30 from each district) were trained to deliver the Ndingathe intervention during the pilot period. HSAs were selected based on the following criteria 1) received SI training and 2) lived in the district. In each district, half (n=15) of HSAs were paired with two EUs of SI (total EUs per district=30). We selected two so that they could alternate attending

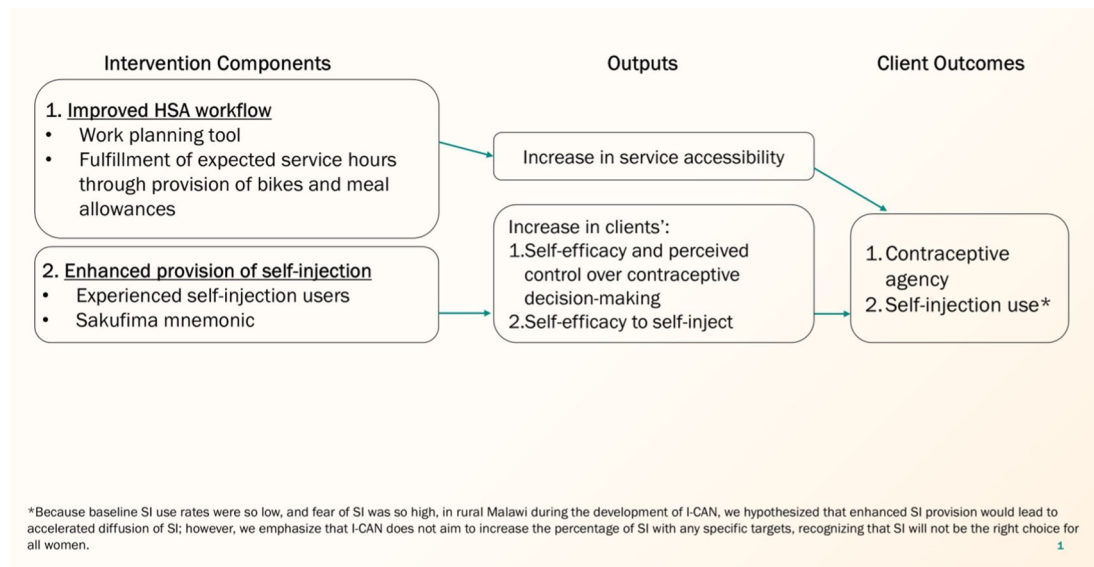


Figure 1. Ndingathe intervention theory of action.

outreach clinics. The 15 HSAs per district not paired with EUs delivered a reduced intervention package including the improved workflow and SI mnemonic. This design was chosen to enable exploratory comparison of feasibility and acceptability of Ndingathe with and without the experienced SI users, to determine whether future iterations of the intervention should include recruiting and training this cadre of lay support person.

Alongside pilot implementation, we collected cross-sectional qualitative and quantitative data from September 2023 to February 2024 to assess the intervention's feasibility, acceptability, and potential effectiveness from the perspective of multi-level stakeholders, including contraception clients, HSAs, EUs, Family Planning Coordinators, and District Health Officers. Family Planning Coordinators and District Health Officers play crucial roles in ensuring the delivery of healthcare services, including family planning and reproductive health.

Sampling and data collection procedures

Surveys with outreach clinic clients

Research assistants attended outreach clinics to recruit clients who interacted with Ndingathe-trained HSAs and EUs for surveys during the intervention period. Research assistants attended 1-2 outreach clinics for the entire day for half (n=15) of HSAs in each district with the goal of collecting 10-20 client surveys per HSA. For feasibility reasons, we did not include all HSAs in survey recruitment efforts. RAs approached all clients after their visit with the HSA and screened for eligibility (i.e., had heard the HSA talk about self-injection of DMPA-SC during the outreach clinic and were not already using DMPA-SC for self-injection before the outreach clinic). For women interested in the survey, RAs obtained informed consent before administering the survey in a private location outside during the outreach clinic.

The survey collected data on client experiences receiving services from HSAs and EUs (where applicable) at the outreach clinic to assess acceptability of the intervention from clients' perspectives. For clients who attended outreach clinics where EUs were present, the survey instrument included a measure of clients' self-reported fear of self-injection before and after they saw the EU during the outreach clinic, used to assess potential effectiveness of the intervention women's self-efficacy to self-inject. The survey also included items asking how helpful clients perceived the extended hours of the outreach clinic and the mnemonic to be (both asked on a 5-point Likert scale). The survey was administered by a research assistant in Chichewa and lasted (~30-45 minutes) using a tablet to record the participant's responses. Each participant was given ~\$8 (USD) to compensate them for their time.

Surveys with HSAs

Quantitative data collection activities also included two rounds of surveys with all 60 HSAs who participated in the pilot before intervention-specific training and the launch of the intervention (baseline) and after the end of the intervention (endline) to assess HSAs' perception of the intervention and the degree to which Ndingathe may improve their job experience. Two trained research assistants collected HSAs' survey responses using Kobo Tool Box, an online survey platform on tablets. HSAs were recruited to participate in baseline surveys during the pilot training and in endline surveys during the closing ceremony of the pilot program.

The survey instrument included measures of role conflict, role overload, and job satisfaction adapted from validated scales used in the United States and in Malawi,²⁴ in addition to items assessing feasibility and acceptability of the intervention from HSAs' perspective. Role conflict is when employees face contradictory expectations and struggle to meet demands, leading to negative outcomes like reduced motivation and productivity.²⁴ Role overload is when an employee is tasked with more than they can handle. Job satisfaction is when an employee is content with their job.²⁵ The role conflict score was measured using a validated scale entitled Role Conflict and Ambiguity in Complex Organizations. This scale includes 8 Likert items on a five-point scale (1= 'strongly disagree' and 5= 'strongly disagree') in which higher scores denoted higher conflict. Role overload was measured including 10 Likert items on a 5-point scale (1= 'strongly disagree' and 5= 'strongly disagree') with higher scores denoting higher overload. Job satisfaction was measured using the Minnesota Satisfaction Questionnaire, a 10-item scale with 5-point response scale ranging from 1= 'very dissatisfied' to 5= 'very satisfied' previously adapted for Malawi to measure HSAs' job satisfaction.²⁵ The instrument also captured the average number of outreach clinics HSAs conduct per week to assess potential effectiveness of the intervention on improving service accessibility.

In-depth interviews with clients, HSAs, experienced SI users, and other stakeholders

To triangulate quantitative survey data on feasibility and acceptability of the intervention with qualitative data on women's experiences, we invited 20 women who were surveyed about their experience at the outreach clinic and an

additional 20 women who had received follow-up from an experienced user after 3 months to participate in an in-depth interview. We purposively sampled clients to ensure equal representation of women under the age of 25 and over the age of 25.

To triangulate quantitative survey data on feasibility and acceptability from HSAs' surveys with qualitative data on HSAs' experiences with the pilot, we also conducted 20 interviews with HSAs who conducted the most outreaches (chosen to understand how the intervention enabled this increase) and 20 interviews with the experienced users they were paired with. To assess acceptability and feasibility of the intervention from other health system stakeholders' perspective, we invited each family planning coordinator and district health officer from pilot districts to participate in an in-depth interview.

All participants provided written informed consent before conducting the interviews. Interviews were conducted by trained research assistants in participant's homes. The average length of the interviews was ~40 minutes. Participants received \$8 in compensation for their time. Interviews were audio recorded and transcribed and translated.

Observations

To assess the potential effectiveness of Ndingathe in encouraging HSAs to provide outreach clinics later into the afternoon, and to gauge the degree to which women attended later in the afternoon when given the option, we conducted 20 observations of outreach clinics throughout the pilot. Research assistants attended the clinics based on when they were scheduled throughout the week. The research staff did not record identifiable information during the observations. Research staff collected data on the number of clients by time of day using an observation template.

Data analysis

Quantitative

The HSA and client surveys were analyzed using Stata. We generated descriptive statistics for sociodemographics and survey items related to acceptability and potential effectiveness. Wilcoxon signed-rank tests were conducted to evaluate the differences in clients' report of their fear of needles before and after talking to an experienced user (among those who had interacted with an experienced user). We conducted paired t-tests of HSAs' role overload, role conflict, and job satisfaction scores pre- and post-pilot.

Qualitative

The client interviews were analyzed using a line-by-line coding process facilitated by a codebook. We developed the initial coding framework deductively, grounded in the topics outlined in the interview guide related to acceptability and potential effectiveness of women's interactions with HSAs at the outreach clinic and self-injection training in line with our theory of action (Figure 1). A multidisciplinary team of five researchers (TJ, MN, MK, IM, JV) coded the transcripts using Dedoose, a qualitative data analysis software. This collaborative approach allowed us to incorporate diverse perspectives and ensure cultural relevance and sensitivity in the coding process. The team held initial meetings to discuss coding discrepancies and refine the codebook. Following coding, the five researchers wrote up code summaries and developed themes.

We analyzed the HSA and experienced user interviews using a rapid framework analysis approach without formal coding. This method allowed us to systematically map and interpret the data in relation to the predefined research objectives. The framework analysis involved five key stages: familiarization with the data, identifying a thematic framework, indexing (applying the framework to the data), charting (rearranging the data according to the framework), and mapping and interpretation to generate insights.

Ethics and consent

The University of California, San Francisco Institutional Review Board (approval date: August 9, 2023, IRB number 23-38982) and Malawi University of Science and Technology Research Ethics Committee (approval date June 5, 2023, IRB number P.03/2020/007) reviewed and approved of this study. Written informed consent was obtained from all participants in the study.

Results

Participant characteristics

Table 1 and Table 2 display the sociodemographic characteristics of the clients and HSAs surveyed and interviewed. More than half of the client survey sample was between the ages of 25-45 (51.7% in Mulanje and 60.8% in Ntchisi), with primary education (74.3% in Mulanje and 10.2% in Ntchisi), and attending the outreach clinic to switch methods (50.3% in Mulanje and 72.3% in Ntchisi) (Table 1). Most HSAs surveyed were male (70% in Mulanje, 60% in Ntchisi) with 10 plus years of working experience (83.3% in Mulanje and 86.6% in Ntchisi) (Table 2). We did not collect demographic information from the family planning coordinators and the district health officers interviewed from each study district.

The results of this evaluation are organized by intervention component. We present themes related to the acceptability, feasibility, and potential effectiveness of the workflow components (work planning template, bikes, and lunch allowance) from the perspectives of clients, HSAs, and experienced users first, followed by results on the enhanced SI provision components (SI mnemonic and experienced SI users).

Table 1. Characteristics of clients surveyed (N=450) and interviewed (N=20).

	Mulanje district		Ntchisi district	
	Surveyed (N%)	Interviewed (N%)	Surveyed (N%)	Interviewed (N%)
Age				
15-24 years	109 (48.3)	8 (20)	88 (39.2)	15 (37.5)
25-45 years	117 (51.7)	12 (80)	135 (60.8)	25 (62.5)
Education level				
No formal education	9 (3.9)	15 (37.5)	2 (1.0)	8 (20)
Primary education	168 (74.3)	20 (50)	156 (70.2)	16 (40)
Secondary education	49 (21.6)	5 (12.5)	64 (28.8)	16 (40)
Visit reason				
Starting FP method for the first time	38 (16.8)	Not collected	28 (12.5)	Not collected
Continuing same method	73 (32.3)		32 (14.2)	
Switching FP methods	116 (51.3)		162 (72.3)	
Interaction at outreach clinic				
Additionally talked to an <i>experienced user</i>	121 (50.3)	10 (50)	120 (49.7)	10 (50)
Only talked to an HSA	105 (50.3)	10 (50)	104 (49.7)	10 (50)

Table 2. Characteristics of HSAs surveyed (N=30) and interviewed (N=10).

	Mulanje		Ntchisi	
	Surveyed (N%)	Interviewed (N%)	Surveyed (N%)	Interviewed (N%)
Gender				
Male	21 (70)	5 (50)	18 (60)	5 (50)
Female	9 (30)	5 (50)	12 (40)	5 (50)
Age				
34-44	14 (46.6)	6 (60)	15 (50)	3 (30)
45-54	16 (53.3)	4 (40)	15 (50)	7 (70)
Years of service				
5-10 years	5 (16.6)	5 (50)	4 (13.4)	4 (40)
10-20 years	25 (83.3)	5 (50)	26 (86.6)	6 (60)

Evaluation of the workflow components of Ndingathe

a) Potential effectiveness of the workflow components

Related to the first pathway in our theory of action (Figure 1) on workflow components increasing service accessibility, Figure 2 depicts a higher percentage of HSAs who reported in post-pilot surveys that they conducted an outreach clinic the recommended amount of 1-5 times a week during the intervention, compared to what they reported in pre-pilot surveys (94% versus 57%, $p < 0.05$). Our observational data showed that 70% of women attended outreaches in the morning and 30% attended in the afternoon, suggesting that offering afternoon clinics was helpful in improving accessibility for some women.

b) Acceptability of workflow components from clients' perspective

The lengthening of HSA outreach hours into the afternoon was seen as highly acceptable by clients. In surveys, 98% (N=442) of clients found it helpful to have the option to attend an outreach in the morning or in the afternoon. In interviews, many clients described appreciating the extended outreach clinic hours because they could work or run errands in the morning and then access family planning services in the afternoon, providing greater convenience and flexibility in managing their daily responsibilities, as noted by a client in Ntchisi:

They did well because in the past when you miss in the morning and get there by 11, you could find them [HSAs] gone. But now it is good because you can go to the farm, or you can go to the market, and still you can find the health surveillance assistants right there, so, it is very good because you can do your errands, two or three of them then come back here. – 22-year-old client, married, from Ntchisi

c) Acceptability and feasibility of workflow components from HSAs' and health system stakeholders' perspective

We found evidence of acceptability of the work planning template among HSAs, with many sharing in interviews that the introduction of structured work plans significantly enhanced the organization of their schedules. HSAs described that, prior to adopting these plans, they would just plan their activities without a structured approach, which led to inconsistent service delivery of outreach clinics in the community. With a predefined schedule, they described planning and carried out their duties more systematically. Several HSAs from Mulanje described that the work plan was easy to follow:

Having that thing directed us on where we were supposed to go every day. We worked so well, and the people were helped. – HSA from Mulanje

It helped us to plan our programs in time and appropriately, and it was not difficult for us to follow because it was serving as a guide that we could easily know that this week, this is how we are going to work. – HSA from Mulanje

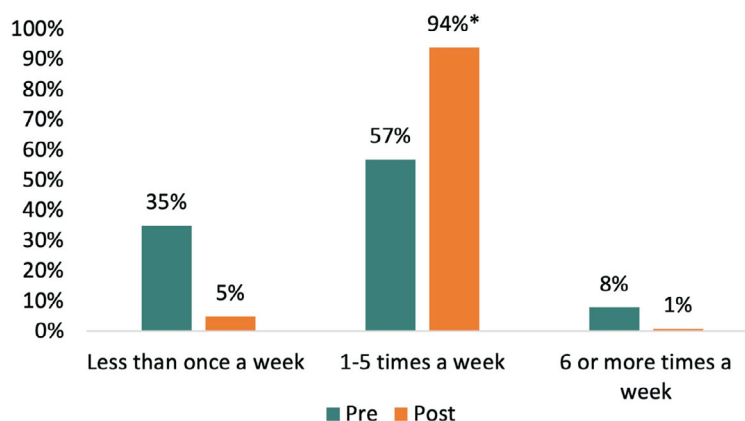


Figure 2. Self-reported frequency of HSAs conducting outreach clinics, from pre/post surveys with HSAs in the pilot (N=60). * $p < 0.05$ using paired t-test.

Several HSAs also noted that the workplan helped them proactively plan ahead for their work week; for example, one stated:

The outreach was many because I could have a clinic for depo per week and other clinics on later days but I was not working under pressure. I had my fixed time such that the programs were not contradicting because I was guided by the work plan. – HSA from Mulanje

HSAs expressed strong willingness to continue using the bi-weekly work plans even after the pilot, acknowledging its feasibility. Many HSAs mentioned that they would find a way to make or print their own plans; for example, one stated:

We realized that the workplanning is a good thing because the schedule will be helping us to work easily. If the office does not supply, we have two or three copies which one can photocopy so that it can continue amongst us, instead of stopping altogether just because the pilot has ended.– HSA from Mulanje

Yes, it is possible to continue to use the bi-weekly plans even without printed weekly plan, we will improvise using the papers we have now. – HSA from Mulanje

Regarding the provision of bicycles and lunch allowance, we found evidence of acceptability from interviews with HSAs describing that it facilitated their commute to outreach clinics and enabled them to stay longer at clinics without worries about transportation or sustenance. Several HSAs mentioned that these structural elements were conducive to extending their outreach clinic services. For example, one noted:

The lunch allowance helped us to visit sites far from our homes of residence. It helped us not to think of knocking off at 12 o'clock, to prepare lunch at home, we just go around the community, find food, eat then get back to work until 4 o'clock. On the bike part, it helped us in transportation. From where we reside to the place of work, it helped us to reach our places of work in time, and when knocking off. And reached our home of residence in time. – HSA from Ntchisi

However, some HSAs mentioned that delays in allowance payments from the study team created significant challenges, often leaving them to conduct multiple clinics without the promised financial support. This not only disrupted program implementation, but also undermined morale and motivation, highlighting the importance of timely compensation to sustain effective service delivery.

What I did not like was that we were told that we would be given the money at the beginning of the program, but sometimes we would come to the middle of the month without the allowance and maybe conduct 2 or 3 clinics without it, so it was disturbing. – HSA from Mulanje

HSAs highlighted that the bicycles significantly impacted their commute, allowing them to reach distant villages efficiently. Even after program completion, the continued use of bicycles underscores their critical role in supporting ongoing health outreach efforts, demonstrating the feasibility and sustained impact of integrating bicycles into health outreach initiatives. Several HSAs mentioned that they would continue to use the bicycles to provide health services:

We do outreach clinics and other tasks as health workers just because of the bike. And if the village is located at a long distance, the bike would help us. We can say that while the program has ended, the bike is still there and we are still using it for our purpose – HSA from Ntchisi

Other health system stakeholders mentioned that there is a recognized need for ongoing support from the District Health Management Team and sufficient resources, such as stationery, bicycles, and lunch allowances, to ensure HSAs can effectively carry out their work in the community.

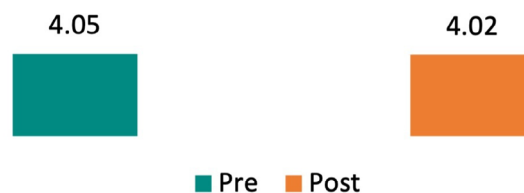
We need stationery, photocopiers, and printers. Only one photocopier is working at this whole facility, making it difficult to provide work plans. – HSA from Mulanje

Related to HSAs' perception of their job, we found significant differences between pre and post role overload and role conflict scores (Figure 3). Specifically, there was a significant decrease in scores on the Role Conflict and Ambiguity in Complex Organizations Scale from 3.70 to 3.18 ($p < 0.05$). We also found that there was a significant decrease in scores on the Role Overload Scale from 3.65 to 3.03 ($p < 0.05$). Scores on the Minnesota Job Satisfaction Questionnaire did not significantly increase after the pilot (See Figure 4).



*p<0.05 in paired t-tests

Figure 3. Changes in HSAs’ self-reported role conflict, role overload, and job satisfaction during the Ndingathe pilot. *p<0.05 in paired t-tests.



P>0.05 in paired t-tests not significant

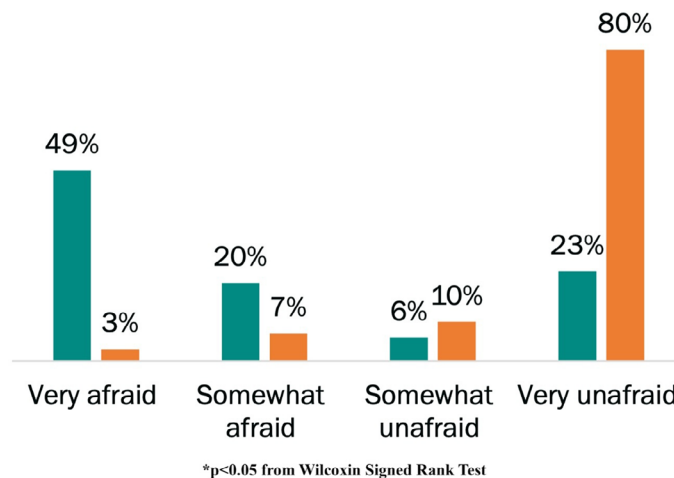
Figure 4. Job satisfaction scores. P>0.05 in paired t-tests not significant.

Evaluation of the enhanced SI provision components of Ndingathe

a) Potential effectiveness of experienced SI users

Related to the second pathway depicted in our theory of action (Figure 1), we found evidence that experienced SI users may improve women’s self-efficacy to self-inject. In cross-sectional surveys with clients, they reported that experienced users helped reduce fears of needles as shown in Figure 5.

In interviews, many clients expressed that the presence of EUs reduced their fear of self-injection. They described EUs as providing reassurance and patiently explained the injection process, even demonstrating their own self-injections to alleviate clients’ concerns.



*p<0.05 from Wilcoxin Signed Rank Test

Figure 5. Clients’ self-reported fear of needles before and after talking to an experienced self-injection user as reported on cross-sectional surveys (N=241)*. *p<0.05 from Wilcoxin Signed Rank Test.

We believed their words that we would be okay. They removed fears from us. – 25 years, Single, Ntchisi

[The EUs] explained their experiences using Sayana. They didn't face any issues with it and they all showed that they were fine in their bodies. Talking to them was encouraging and useful for us. – 31, Married, Ntchisi

In interviews with HSAs', many described that experienced users helped allay fears of self-injection better than they alone could. An HSA from Ntchisi emphasized that women benefitted from peer support from an experienced user:

What made the work easier was that after we taught them, they were also meeting up the experienced users. Unlike when I was alone, it was taking time for a woman to self-inject. But when she sees the experienced user, they were motivated that this one is my fellow woman, then self-inject. – HSA from Ntchisi

b) Acceptability of the SI mnemonic and experienced SI users from the perspective of clients:

The mnemonic was widely accepted by clients, with 95% (N=429) in surveys reporting that it was helpful in guiding them through what the self-injection process would be like. Moreover, many clients mentioned that they liked that the mnemonic was tailored to the local language, as expressed by this client:

It is helpful because SA means mixing the medicine, press slowly, in that way it means we are pressing the injection until it finishes, so we saw that these words are good. – 37 year old client, married, from Mulanje

Many clients reported significant encouragement and reassurance from interacting with experienced users regarding self-injection. The guidance provided by EUs, including step-by-step instructions and safety assurances, was invaluable for many clients. This support enabled clients to feel confident in their ability to self-inject, which many felt they could not do independently:

It was helpful that the experienced user was reminding us to shake the SAYANA vigorously. Then they said handle it properly as we injected ourselves. In simple terms, they were reminding us of the process To me, I think there was a benefit because without the experienced user we would not know. – 28 years, Married, Ntchisi district

Regarding follow up support, clients who had received follow-up visits from the experienced user expressed appreciation. They described these visits providing an additional layer of support, reassurance, and continuity of care, making clients feel valued and cared for in their self-injection journey, as expressed by these two clients:

I felt happy and remembered because the EU followed up with me. If it were others, they might have remained silent after the self-injection. – 28, Married, Ntchisi District

The expert women visited us at home, asked about any problems, and ensured our well-being, which was very reassuring.– 22, Married, Ntchisi District

Clients appreciated the reminders and additional guidance, which helped them maintain proper self-injection practices. Clients in Ntchisi and Mulanje both noted in the interviews the helpfulness of the reminders they received:

The EUs helped us a lot by reminding us of the steps during reinjection, making us feel supported. – 32, Married, Mulanje

I was very happy because when they came it was like they have reminded me what we used to learn when we meet them, so, they reminded me once again and I was refreshed. It was helpful because sometimes a person forgets due to being busy, so, they reminded me that aa I have remembered what I am supposed to do and follow it. – 22, Married, Ntchisi district

The follow-up visits also fostered a sense of trust between the clients and the EUs. This relationship encouraged many clients to reach out for support and guidance whenever needed, knowing they had reliable and approachable contacts, as described by these clients:

I was happy to open up to these women. If it were at the hospital, it would have been a long process, but I could just call them when needed. – 36, Married, Mulanje

I felt good, and my husband also felt honored to be present during the visit. It made us feel supported. – 38, Married, Mulanje

c) Acceptability and feasibility of the mnemonic and EUs, from HSAs' and EUs' perspective

Related to the mnemonic, HSAs shared in interviews that the SAKUFIMA mnemonic was easy for women to remember because it sounded like a person's name or a song. This made the acronym relatable and simple to recall during self-injection. HSAs reported that women generally reacted positively to the acronym. They found it interesting and enjoyable, which facilitated their engagement with the self-injection process.

Because the acronym sounds like a person's name or a song, it is easy for the women to remember it. – HSA

HSAs also frequently mentioned that using the acronym saved time. It reduced the need for lengthy explanations and repetitive training sessions, as women could quickly grasp and remember the self-injection steps.

It was time saving because instead of explaining the steps it was in short form and people understood easily. When teaching a woman this mnemonic, she was paying full attention to understand so we were saving time because few questions were asked, showing that she had understood at the beginning. – HSA from Mulanje

One HSA, interviewed after the pilot's completion, emphasized the ongoing use of the mnemonic, stating,

We are continuing in spite of the program ending but we are telling women about sakufima so that they should not have difficulties to remember how to self-inject. – HSA from Mulanje

In terms of feasibility of the EU component, many HSAs reported that their work was easier and more effective when partnered with experienced users at the outreach clinics. Experienced users helped create a supportive environment where clients felt more comfortable and open to learning about and trying self-injection. This peer-driven approach not only speeds up the HSAs' teaching process but also increases client motivation and trust as described by an HSA from Ntchisi.

Okay, what made the work easier was that after we taught them, they were also meeting up the experienced users. Unlike when I was alone, it was taking time for a woman to self-inject. Maybe even telling you that I will just get some medications to self-inject at home, that's where you were advising them that aaaah you are supposed to self-inject right here. But when she sees the experienced user, they were motivated that this one is my fellow woman, then self-inject. HSA from Ntchisi

Experienced users described appreciating the Ndingathe program in interviews, with many mentioning that they felt proud to be a role model for other women to learn how to self-inject in their community. Many experienced users also mentioned that by sharing their own experiences, clients became more open to share their fears with them. And in some cases, women were more open and forthright with the experienced users compared to HSAs. As two described:

What made me happy is that I was brave enough to self-inject which made other women to be motivated to do the same too. – EU-3 Ntchisi

The benefit is that these women do not travel longer distances to seek for these family planning services from the HSA, and also it gets rid of their fears such that whenever they are with us they become more open than when they are with the HSA. – EU-4 Ntchisi

When asked about the feasibility of conducting follow-up visits to women interested in self-injection support, most experienced users interviewed reported that it was easy to follow up with women because they lived in the same village. Many of them also expressed that they would like to participate if the program continues. As stated by one:

It was very possible because we were in the same village. If the program extends, I will be very happy as I will continue doing the work that I was doing because some people benefited from the information that I gave them – EU-2 Mulanje

Discussion

This cross-sectional, mixed methods evaluation of a pilot of the HCD-derived Ndingathe intervention found Ndingathe to be feasible to implement and acceptable from the point of view of women, HSAs, and experienced users of self-injection in two rural study sites in Malawi. Our findings also suggest that the intervention may be effective in improving the accessibility of outreach services and in reducing women's fear of self-injection, both of which—per our theory of action—can increase women's agency related to contraceptive decisions. Thus, Ndingathe shows promise as an approach to improving the accessibility of contraception outreach services in rural areas and enhancing counseling and follow-up for SI of DMPA-SC to support more women to benefit from this unique self-care technology.

Ndingathe is unique among programs to improve contraceptive care in addressing fundamental structural issues that restrict women's access to community health workers in the most rural areas.⁵ For instance, the program helped mitigate transportation challenges by equipping HSAs with bicycles, which allowed them to reach more remote areas and follow up with clients in their homes, a strategy that has shown promise for improving community health outreach in other rural settings in sub-Saharan Africa.²⁶ Furthermore, providing HSAs with lunch allowances has been demonstrated in other studies to improve the efficiency of community health workers by addressing the financial barriers they face when conducting outreach.²⁷ Addressing these structural challenges is critical to ensuring the sustainability and scalability of contraceptive access interventions like Ndingathe, as they directly impact HSAs' ability to conduct outreach clinics in rural areas.

The feasibility of self-injection programs, particularly in resource-limited settings, has been a topic of considerable debate. Studies like those by Cover et al. have demonstrated that self-injection of contraceptives is highly feasible in low-resource settings, as it allows women greater autonomy and reduces the burden on healthcare systems.²⁸ Nonetheless, Keith et al. point out that while self-injection offers greater convenience, ensuring sustained adherence requires continued support, follow-up, and training.¹⁹ In our study, the follow-up visits conducted by experienced users were key to maintaining client engagement and adherence to proper self-injection practices. This approach aligns with Keith et al.'s recommendation that continuous community-based support is critical to the success of self-injection programs, particularly in settings where access to formal healthcare is limited.¹⁹ We also innovated existing SI programming by developing a mnemonic for the critical self-injection steps. The mnemonic is not only practical but also integral to supporting women's confidence and ability to self-inject correctly. The continued dissemination of the mnemonic by HSAs after the formal end of the pilot, before we interviewed them, underscores its value and the ease with which it can be integrated into routine practice, thereby enhancing the feasibility of its long-term use in self-injection programs.

We enhanced self-injection programming by leveraging peer support—pairing EUs of SI with half of the HSAs participating in the pilot. Our experience showed that this component of the intervention was highly valued by all involved and we recommend retaining this in future implementation or adaptation efforts of Ndingathe. The involvement of experienced users in the Ndingathe program and their role in increasing client confidence is strongly supported by research on peer-led health interventions. Evidence suggests that peer support can have a positive impact on a client's knowledge of family planning methods and contraceptive use.^{29,30} Studies have consistently found that peer support enhances the acceptability of new health behaviors by creating a trusting and relatable environment.^{31,32} In our study, experienced users not only alleviated fears but also provided practical, ongoing support that extended beyond the clinical setting. Their ability to follow up with clients in their homes and provide continuous reinforcement of self-injection techniques aligns with findings that peer interventions are most effective when they offer both emotional and practical support. However, some studies suggest that peer support is not always universally accepted. Campbell et al. found that in certain rural communities, social hierarchies and cultural norms may limit the effectiveness of peer interventions, as clients might feel uncomfortable receiving health advice from peers.³³ In our case, the peer-driven approach was developed through a participatory community design process and generally well-received.

The role of HSAs in self-injection in our study reflects broader trends in task-shifting in global health, where community health workers take on expanded responsibilities to alleviate workforce shortages. Task-shifting has been particularly successful in reproductive health interventions, where HSAs and other community health workers are trained to provide contraceptive services in rural areas. Perry et al. emphasize that community health workers play a crucial role in increasing access to contraceptives and improving health outcomes in low-resource settings.⁸ However, the success of task-shifting models depends on adequate training, supervision, and support for community health workers. In our study, the addition of experienced users working alongside HSAs eased the burden on HSAs, allowing them to work more efficiently. This peer-driven approach not only empowered clients but also helped alleviate the time pressures faced by HSAs, echoing findings by Ballard et al. that collaboration between community health workers and peer supporters enhances the effectiveness of healthcare delivery.³⁴

While the Ndingathe pilot showed promising results, there are several limitations to our study that must be acknowledged. First, the study lacked a control group and thus our findings on potential effectiveness are exploratory and should be followed up on in future testing. We also lacked measures of self-efficacy and perceived control over contraceptive decision-making—an output from the theory of action directly related to the hypothesized impact on contraceptive agency²²—which merits further investigation. Second, the development and piloting of Ndingathe was done in two specific rural districts in Malawi, and generalizability to other areas of the country—or other rural settings in sub-Saharan Africa—is unknown. Third, stockouts of DMPA-SC occurred during the intervention period, making it difficult to our intended implementation approach in a context where women can access units for self-injection if they choose to do so. Lastly, we only spoke to HSA who conducted most outreaches and are limited in knowing about those who conducted less outreaches.

Conclusion

These findings are promising and highlight the potential of Ndingathe to address critical gaps in contraceptive access and support for women and adolescents in rural Malawi. Overall, the findings from the Ndingathe pilot align with much of the existing literature on self-injection, peer support, and task-shifting in reproductive health, and suggest that the combination of addressing CHWs' structural challenges while pairing them with peer counselors may be uniquely promising in the context of rural contraception access. The use of the SAKUFIMA mnemonic and the involvement of experienced users were both highly acceptable and feasible components that significantly improved the success of the intervention. While these initial results are encouraging, further testing is warranted to establish the effectiveness of the solution in achieving its intended outcomes, such as improved contraceptive agency. Additionally, efforts should be made to explore whether this model could be adapted and implemented in rural settings in other countries facing similar challenges, further contributing to global efforts to improve access to contraception services.

Thinking ahead to potential scale-up of the model, as highlighted by district health officials in the pilot, sustained support and follow-up for the intervention will be essential for long-term success, a theme echoed in other studies on self-injection and contraceptive delivery programs.

Data availability

In our grant agreement with Bill and Melinda Gates Foundation, we have agreed that quantitative data will be made publicly accessible six months after publication of the results in a peer-reviewed journal. For qualitative data, our agreement with BMGF does not require that we make transcripts publicly available due to the need to ensure a high degree of respondent confidentiality.

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