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Resilience after withdrawing a technology-based medication adherence support intervention from people living with HIV in rural Uganda

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Abstract

Technology-based interventions for behavior change, such as adherence monitors and SMS text messages, can improve adherence to HIV antiretroviral therapy. It is unclear, however, how the effects of such interventions are maintained when interventions are withdrawn. We explored resiliency of people living with HIV in coping with adherence to antiretroviral therapy (ART) after withdrawing an adherence support intervention of real-time adherence monitors linked to SMS text messages at study closure. This is a qualitative study conducted with former participants of a pilot randomized controlled trial after study closure. Between April 2016 and November 2016, we used convenient sampling to interview 28 of the 62 participants from the pilot trial, which was conducted in rural Uganda. Interviews elicited information on experiences of taking ART in the absence of the intervention, coping strategies, and changes in social support interactions. Data were analyzed inductively using content analysis.

Most participants demonstrated resilience through learning adherence from the intervention; and internalizing the habit of medication adherence. They seemed to have a sense of self-esteem, positive thinking, and access to supportive relationships. Other participants employed adaptive coping strategies, such as using alternative cues (e.g., alarms), accessing spiritual support, and adjusting their medication time to their routine. A few participants lacked resiliency, lost the habit and struggled with adherence. They were dependent on the intervention, appeared isolated and psychologically stressed, and were unable to overcome challenges associated with poor social support systems. Intervention-related benefits may or may not persist after the intervention is withdrawn. Contingent on individuals" underlying characteristics and relationships, participants manifested resiliency through learning and internalization, as well as using alternative coping strategies. Such resiliency could facilitate the use of short-term interventions, which are

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particularly important for resource-limited settings. Participants should be referred to available additional support at study closure when needed.

Keywords

Resilience; post-intervention experiences; real-time adherence monitoring; sustaining behavior; intervention dependence

Introduction

Mobile health interventions such as those utilizing SMS text messages can help establish behavior or foster behavior change to promote adherence to medications, including HIV antiretroviral therapy – ART (Mbuagbaw et al., 2013), contraceptive use (Jones, Hoover, & Lacroix, 2013), antenatal care attendance (Sondaal et al., 2016), and smoking cessation (Whittaker et al., 2012). Real-time wireless adherence monitors (i.e., medication containers that record a date-and-time stamp when opened and transmit this data to a central server over cellular networks) can trigger the timely implementation of behavior change interventions (Haberer et al., 2010). Real-time adherence monitoring combined with mobile phone-based SMS reminders have been shown to improve adherence to ART (Haberer et al., 2016; Sabin et al., 2015).

The underlying goal of adherence interventions is to enable internalization of consistent medication-taking behavior, and facilitate self-management of disease (Cooper, Clatworthy, Whetham, & Consortium, 2017). Most studies, however, only assess the impact of an intervention while in use, yet interventions are typically supported for a time-limited period and/or are withdrawn at study closure. Reasons for intervention withdrawal include: 1) the need to conform to the study design and research ethics requirements, especially if leaving such interventions can potentially mislead or harm participants; 2) lack of economic feasibility in continuing to support the intervention after the study period has ended; and 3) the need to re-use the intervention in a different population group. The effects on behavior after withdrawal of the intervention are often unknown. Participants, especially those whose behavior was positively affected by the intervention could experience challenges because of dependence on the intervention and thus experience poor outcomes, while others may display resilience through the desired internalization of adherence behavior and do well.

We conducted a pilot randomized controlled trial that deployed SMS text messages, and real-time adherence monitoring to support adherence among individuals initiating ART in rural Uganda. For the purpose of this manuscript, the pilot randomized controlled trial is known as the Wisepill Intervention Study (Parent Study). Findings indicated that daily and then weekly scheduled SMS reminders improved adherence compared with real-time monitoring alone, whereas SMS reminders linked to late or missed doses did not; no clear benefit was seen with SMS notifications of nonadherence sent to family or friends for social support (Haberer et al., 2016). To understand the durability of any intervention effects and explore participants' resiliency to and experiences with intervention withdrawal, we conducted a follow-up study consisting of qualitative interviews among participants of the Wisepill Intervention Study two years after study closure. To the best of our knowledge, this

is the first study to assess post-intervention experiences following the withdrawal of technology-based adherence support intervention. In this paper, we use resiliency to mean the ability of people living with HIV to cope with anti-retroviral adherence after withdrawing the adherence support intervention.

Methods

The Wisepill intervention study (Parent study)

Between September 2013 and October 2015, we carried out a pilot randomized controlled trial (called the Wise-pill Intervention Study) exploring the effects of different types of SMS plus real-time adherence monitoring on ART adherence among 62 individuals living with HIV in rural Uganda.

The Wisepill Intervention Study involved two types of participants: individuals taking ART ("study participants") and individuals providing support to the study participants (e.g., help with taking medications; "social supporters"). Study participants were recruited from the Immune Suppression Syndrome Clinic at Mbarara Regional Referral Hospital (MRRH) – a rural public hospital that dispenses free ART to over 10,000 people living with HIV in southwestern Uganda. The study involved a real-time adherence monitor (Wisepill; a pill bottle which records a date-and-time stamp when an individual opens it to take pills), SMS reminders to study participants and SMS notifications to social supporters. Participants were randomized 1:1:1 as follows:

1. Scheduled SMS plus real-time adherence monitoring ("scheduled SMS arm") – Study participants received an SMS reminder daily for one month, then weekly for two months. For the next six months, study participants received an SMS only if no signal was received from the monitor within two hours of the expected dosing time, and an SMS notification was sent to one to two social supporters if no signal was received for more than 48 hours.
2. Triggered SMS plus real-time adherence monitoring ("triggered SMS arm") – For the entire nine-month study period, study participants received an SMS only if no signal was received from the monitor within two hours of the expected dosing time. For the latter six of the nine months, an SMS notification was sent to one to two social supporters if no signal was received for >48 hours.
3. Real-time adherence monitoring only (called the "control arm") – Study participants in this arm received no SMS reminders.

As previously published, adherence significantly improved by approximately 11% for participants receiving scheduled SMS reminders that were sent daily and then weekly when compared to participants in the control group; the corresponding mean (standard deviation) adherence levels were 90% (8.9) and 79% (22) (Haberer et al., 2016). No clear benefit was seen from SMS notifications sent to social supporters.

The interventions were acceptable (Musiimenta et al., 2018), and encouraged medication adherence through habit formation and a desire to show commitment to taking medication (Ware et al., 2016).

The follow-up study interviews to assess intervention withdrawal

The research assistant who was bilingual in English and the local language (Runyankole), and trained in qualitative research and research ethics carried out face-to-face semi-structured in-depth interviews with participants of the follow-up study. The interviews were carried out using a convenience sample because we wanted to understand a range of experiences after withdrawal of the intervention; we conducted interviews until thematic saturation was achieved. Participants were recruited sequentially from the telephone register that we had compiled during the Wisepill Intervention Study. The mean (standard deviation) of time that had elapsed between the closure of the parent study and the qualitative interviews for the follow-up study was 2.0 (0.33) years. Per standard practice for research studies in this setting, each participant was given a transport refund to cover the cost of transport to the study site (up to US $4), and a small incentive (e.g., a bar of soap) to compensate for the time offered to participate in interviews. Interviews were conducted two years after the intervention study concluded – between April 2016 and November 2016. Interviews were carried out at the research office, participants' homes, or any other place preferred by the participants. Interviews lasted between 45 minutes and 60 minutes, and were carried out until thematic saturation was achieved (i.e., until no new data was obtained. Interviews elicited information on experiences of taking ART in the absence of the intervention; changes in social support interactions; the process of withdrawing the intervention; and recommendations for future use of the intervention. Sample open-ended questions include: I would like to start by asking about your experience taking medication since the study ended. Since we took away the device and stopped the SMS text, how hard/easy has it been for you to take your medicine? How did you feel when we took away the Wisepill device and stopped the SMS? The research investigators reviewed transcripts for quality, clarity, and detail. Participants' identification numbers rather than names were used on transcripts to maintain confidentiality. Interviews were conducted in the local language (Runyankole), audio-recorded, and transcribed in English for analysis.

Data analysis

Data were analyzed inductively using content analysis (Hsieh & Shannon, 2005). We used an open approach to data by reading transcripts line by line to identify and name sections of text that were judged to demonstrate participants' experiences of taking medication after withdrawing the intervention as well as their experience about the process of withdrawing the intervention. This process resulted in a code book which was developed by authors AM and TW and reviewed by JEH. Discrepancies of interpretation (approximately 15%) were resolved through discussion until consensus was achieved. AM and TW developed the final codes with significant input from JEH. The final codebook was composed of relevant content, operational definitions, and illustrative quotes developed after iteratively reviewing interview transcripts. After importing the codebook to NVIVO software version 11, AM and TW used the software to code all the interviews. Coded data were used to iteratively develop high-level conceptual themes/categories corresponding to key aspects of participant experiences. The categories are presented as results, below.

Ethical approval

Ethical approvals for the parent and follow-up studies were obtained from the Research Ethics Committee of Mbarara University of Science and Technology, the Uganda National Council for Science and Technology, and the Partners Human Research Committee for Massachusetts General Hospital.

Results

Participant characteristics

We attempted to contact a total of 33 participants from the Wisepill Intervention Study; however, five phone numbers were non-functional. We conducted interviews until thematic saturation, which occurred after the 28th participant. The majority of the participants in the post-intervention study (16/28 [57%]) and the Wisepill Intervention Study (40/62 [65%]) were women. The median age for participants in the post-intervention study was 37 years, while that of the Wisepill Intervention Study was 31. The majority of participants in the post-intervention study (23/28 [93%]) and the Wisepill Intervention Study (60/28 [97%]) were able to read English or Runyankole. In the post-intervention study, 13 (46%) participants were in the schedule arm, 10(36%) in the triggered arm, while 5 (18%) were from the control arm.

As further described below, three themes emerged from the data, indicating the demonstration of resilience by participants. These themes are: *learning adherence from the intervention*; *internalizing the habit of medication adherence*, and *adapting coping strategies*.

Participants who were resilient appeared to have self-esteem and pride through continued adherence and had access to supportive relationships. Lack of resiliency was demonstrated through *intervention dependence*, which appeared to be characterized by participants' feelings of isolation and psychological stress, and, poor social support systems.

Learning adherence from the intervention

Participants' knowledge of being "watched" by the monitor inspired them to adhere to their medication, which was reinforced by a desire to show their adherence to the researchers through the real-time monitors. Participants demonstrated resilience through learning how to consistently take medication from the real-time monitor. They felt the monitor had "finished its job of teaching" them how to adhere to medication, and they can now remind themselves. They recommended using the monitor to teach medication adherence to other people, especially those who are not yet accustomed to adhering to medication:

> Because you see when you are giving them to us you tell us that we are going to be watched so this forces us to take the medication because you know that they are watching you but it reaches at point and you realize that it has finished its job of reminding and you can now remember on your own. (male, triggered arm)

Using triggered SMS reminders also trained participants to adhere to ART. They had to take medication on time to avoid being sent SMS reminders that were linked to missed doses.

Participants thought that receiving reminders linked to missed doses would indicate lack of commitment to medication adherence:

> I: Did you learn anything from the study?
>
> R: Yes. I learnt adherence because I would try to make sure that I take on time without getting the messages so this helped me to get my mind fixed on the time to take my dose. (male, triggered arm)

Internalizing the habit of adherence: Concurrent implementation of the intervention with initiation of ART enabled participants to get "used" to taking medication as prescribed early on, even after withdrawing the intervention. They were "tamed" by the monitor, and eventually mastered the game of medication adherence:

> I: Okay, now that you don't have the device, do you think your ability to take your ART as prescribed has been better, worse or the same?
>
> R: By the time they took the device, I was already used to taking my drugs well and more still I was given the device the time I was started on medication so there is a way it tamed me well … (female, scheduled arm)

Participants internalized the habit of adhering to ART therapy from the intervention through SMS. They reported that reminder messages "got stuck" in their mind to the extent that even when the messages stopped coming, they could still feel as though they have heard the messages and took the medication on time:

> There is a way that message got stuck in my mind every time it approaches my time for taking drugs, I feel as if I have heard that message in my ears. Even now it's like I have that device because my body feels my time … (female, scheduled arm)

Despite some initial stress, participants reported that the habit of medication adherence habituation gained from the study enabled them to overcome emotional attachments to the intervention:

> I: Tell me how you felt when the device was taken away at the end of the study?
>
> R: Okay I felt stressed because I was used to it because they had told me that when I open it they know that I have opened so that motivated me to open but when they took it away I felt bad but I knew the effect would not be much because I had already been used to taking my medication I knew that I would continue taking my medication. The way I take my medication remained the same. (female, scheduled arm)

Self-esteem and pride through continued adherence

Participants appeared to have a sense of self-esteem and pride as a result of learning from the study. They expressed confidence in their ability to adhere to medication independent of the intervention. Some of them perceived the intervention withdrawal as "closing a school" or "being promoted" from a class of being beginners to another class of patients that adhere to their medication. They associated intervention withdrawal with the realization that their adherence was appropriate. They believed that their adherence was better than for those that

never participated in the study who often returned to the clinic with unexpected pill balances:

> I: Did you learn anything from the study?
>
> R: Yes I learnt how to adhere to my drugs I am not like those who never participated … Us who participated in the study are better because our adherence has been promoted unlike those who never participated
>
> I: How do you know that?
>
> R: I find them having issues with counsellors at the clinic because they don't take their drugs well. (male, triggered arm)
>
> I: Please tell me about your experience taking these drugs after the closure of the study.
>
> R: For me I continued taking my drugs well and happily because I know they are the source of my life. I feel happy when am taking them. (female, control arm)

Participants felt that the study adequately prepared them for the withdrawal of the intervention by informing them of those plans at enrollment.

> I: How would we have prepared you as a person for the study closure?
>
> R: For me I was prepared well because I knew the time the study was to end since I was told everything about that at the beginning and I knew what was going to happen so I did not find any problem with that. (male, triggered arm)

Persistent social support from the intervention

Participants who remained in good relationships with their social supporters after closure of the study, and whose social supporters continued providing social support even without receiving the SMS notifications, reported no challenges in taking medication on time. This strong social support system continued to facilitate medication adherence by providing various relevant support including medication-taking reminders, alcohol cessation advice, counseling about taking medication, transport to the clinic for medication refills; food and drinks; and reminders for returning to the clinic:

> I: What does your social supporter do for you now that the study ended?
>
> R: She is my wife; she cooks for me and cares for the children. She boils for me drinking water and she gives it to me in a cup to use it to take my medication. We discuss our clinic return dates to ensure that we do not to forget … (male, scheduled arm)

Adopting adherence coping strategies

Other participants employed adaptive coping strategies to enable them in continuing to take their medication on time, even after withdrawing the intervention. These coping strategies include seeking new sources of social and spiritual support, and adjusting their medication time to routine, and using alternative cues (e.g., phone/clock alarms, school bells, and radio/television times):

I: What helps you to keep taking your medication on time now that the device was taken away?

R: When the SMS from the study stopped coming, I initially could not take pills on time, but later, I started using the phone alarm and it is the one helping me take pills on time now. (female, scheduled arm)

I: Please tell me what has been easy for you in taking your ART since the study closed?

R: When I realized that am sick I accepted that I have to take my drugs every day of my life. (male, triggered arm)

Intervention dependence

A few participants who lacked resiliency reported being used to the intervention to the extent that they had challenges taking ARTs on time after the closure of the study.

Because the intervention was given to them at a time they were initiating ART medication, it became part of their lives, and they found it hard to adhere to medication without being reminded by the intervention.

I: What has been easy for you as far as taking your ART is concerned?

R: Surely if you are used to Wisepill and they take it away from you it's hard to go the level of taking your drugs well the way it should be because your head is fixed on the Wisepill and you expect SMSs to come … (female, scheduled arm)

Isolation and psychological stress

Participants who lacked resiliency and reported worse adherence after the study closed appeared isolated and psychologically stressed, and wished that the study would continue to support them with adherence. For instance, they suggested continued outreach by study staff to encourage them take their medication well. They interpreted the withdrawal of the intervention as though no one cared for them anymore. They felt isolated and psychologically stressed, and thought their lives were "in danger".

I: Now the SMS reminders were also stopped at a certain point, how did this make you feel?

R: I felt bad. I knew that the people in the study had given up on us … I knew that my life was going to be in danger. I knew that if I have no one to follow me up I will die … I don't take well because I have no one to remind me. (female, triggered arm)

I: So how would we have prepared you for the closure?

R: I think they could have called us and emphasized to us that we should keep taking our drugs o time and keep checking on us to see how we are doing. (female, scheduled arm)

Poor social support systems

Participants who lacked resiliency and reported poor adherence also appeared to have poor social support systems and poverty, which they were unable to overcome. Their social supporters did not continue providing support beyond the study period, mainly due to relationship dynamics and lack of resources.

> I: Now that study is over, do you think your social supporter provides you with more, less or the same support to take your ART?
>
> R: He would take it serious to remind me but when the study ended, he also ended the support. I can't lie to you that he is still reminding me because he stopped.
>
> I: So what does he do for you these days?
>
> R: The only thing he does is to know that I am sick … (female, scheduled arm)

These participants wished that study staff had trained social supporters about the importance of supporting individuals living with HIV adhere to their medication, and encouraged them to continue providing support even after the closure of the study:

> I: How would we have prepared your brother to support you better?
>
> R: They would have called him and encouraged him to keep on reminding me and may be training him in taking care of HIV patients. (female, scheduled arm)

Discussion

This follow-up qualitative study explored the resiliency of people living with HIV in coping with adherence to antiretroviral therapy (ART) after withdrawing an adherence support intervention of real-time adherence monitors linked to SMS text messages at study closure. Results reveal that many participants were resilient to withdrawing real-time ART adherence monitors linked to SMS text messages and reported continued adherence after study closure. These participants demonstrated resilience through learning adherence from the intervention; and internalizing the habit of medication adherence. They seemed to have a sense of self-esteem, positive thinking, and pride, as well as access to supportive relationships. Other participants employed adaptive coping strategies, such as using alternative cues (e.g., alarms), accessing spiritual support, and adjusting their medication time to their routine. A few participants lacked resiliency, lost the habit, and struggled with adherence. They were dependent on the intervention, appeared isolated and psychologically stressed, and were unable to overcome challenges associated with poor social support systems and poverty.

Using the intervention trained participants into the practice of medication adherence, which they maintained even after withdrawing the intervention. The scheduled SMS supported the learned habit of adherence. This learning consequently facilitated resilience that resulted in maintaining medication adherence even after withdrawing the intervention. This experience is consistent with the exercise principle of learning that posits that practice facilitates learning (Ambrose, Bridges, Lovett, DiPietro, & Norman, 2010). Self-esteem and pride

created feelings accomplishments obtained from being adherent. Consistent to the prevailing literature, people often repeat behaviors that lead to positive feelings (Skinner, 2014).

Participants demonstrated resilience through internalizing the habit of medication adherence. Internalization of behavior is often not guaranteed after the end of a health behavior intervention (McKee, Bannon, Kerins, & FitzGerald, 2007). Maintenance of health behaviors is influenced by a variety of complex intertwined factors operating at various levels. These factors include patients' ownership of the behavior, self-determination, availability of social support, and competency (Bellg, 2003). In the current study, participants identified several factors that may have contributed to their success with internalization: reminders for habit formation implemented specifically at the time of initiation of ART, ongoing monitoring that motivated them to adhere, individual capabilities (self-efficacy) to internalize the behavior, social support systems, as well being informed beforehand about the intentions to withdraw the intervention after the study. Further studies using this technology are needed to see if this approach to adherence support is replicable in different contexts and determine the duration of the internalized behavior. Assessment of internalization of behavior at study closure may help determine if additional support services are needed by some participants.

Mobile phone alarms were used as alternative coping strategies for participants who did not internalize behavior by the closure of the study. Setting alarms to remind medication taking at a particular time has previously been suggested as one of the resilience strategies for medication adherence (Furniss, Back, & Blandford, 2012). Phone alarms are free, mobile, and can snooze until medication is taken. This approach can be facilitated by the widespread cell phone ownership and mobile network coverage in sub-Saharan Africa (Pew Research Center, 2015).

Although literature is not highly supportive of the effectiveness of electronic device alarms for ART adherence (de Lima, Galvão, de Oliveira Alexandre, Lima, & de Araújo, 2016), our study indicates that mobile phone alarms may be more helpful as continuation of an internalized ART adherence behavior.

The continuity of social support (e.g., ongoing medication reminders, transport to clinic, food/drinks, and counseling) after the intervention was withdrawn was also a key factor in enabling participants maintain their adherence behaviors. Access to social support has previously been reported as an important factor in coping with HIV in Somalia (Kulane et al., 2017). In our study, continued social support was attributed to social supporters' possession of enough resources and knowledge of the benefits of supporting individuals living with HIV, as well as availability of good relationship between participants, and their social supporters. Generally, as previously identified in the Wisepill Intervention Study (Atukunda et al., 2017), not all relationships are supportive as various circumstances can potentially influence the existence, nature, and frequency of support. It is important to further assess how social environments influence resilience to withdrawing of interventions, and identify characteristics of enabling environments.

Participants whose social supporters withdrew their support after the intervention recommended that social supporters should be oriented about the importance assisting people living with HIV take their medication. Participants whose social supporters did not provide support after the intervention was withdrawn recommended that social supporters should be oriented about the ongoing importance of assisting people living with HIV take their medication.

An assessment of social support status at study closure could help devise a follow-up plan (transition/alternate support systems) that could be availed to participants whose adherence may suffer after withdrawing the intervention. For example, participants may be informed of the available potential linkages to social protection programs, such as livelihood support groups, in order to transition them off the intervention (Cluver et al., 2016; Haberer et al., 2017). Other support systems could include informing participants of the available support services such as referrals to counseling services and spiritual therapy, so that those who require assistance can utilize the services.

We also observed underlying participant characteristics that may explain some of the differences between individuals who were able to adhere well after the study and those who struggled. For instance, when describing the process of internalization and feeling promoted through “school”, participants expressed pride and strength in this accomplishment. Related to this finding, Ironson and Hayward (2008) demonstrate that feelings of optimism influence HIV medication adherence and can lead to better health outcomes. On the other hand, those who reported missing the benefits of the intervention emphasized their isolation and numerous social and physical needs. Asking questions about these feelings may help researchers understand the extent and type of support to provide participants after the study’s closure.

This study has important limitations. First, the study sample was small (28 drawn from 62 participants). The achievement of theme saturation suggests the sample was adequate, but other viewpoints may have been missed and we did not purposively sample participants by their adherence during the trial. Second, the intervention period during the Wisepill Intervention Study was relatively short at nine months; inferences about experiences of participants in studies with longer follow-up may be different.

Finally, since results are obtained from participants’ self-reports, responses might have been influenced by social desirability and/or desire to obtain additional resources, especially given the lack of resources in this study setting. Ongoing objective adherence measurements were not available to compare with the parent study. Long-term monitoring with objective adherence measures would be of interest for future studies.

To the best of our knowledge, this study is the first to report post-intervention experiences following the withdrawal of technology-based antiretroviral adherence support. Our findings are important for understanding how this and potentially other similar interventions can be used to facilitate sustainable ART adherence, as well as for informing optimal study design for future behavioral interventions.

The identified durability of the effects of the intervention on adherence behavior after study closure defines a promising and efficient intervention strategy that may be particularly important for a resource limited setting. Short-term use and recycling of the intervention to other participants after habit formation has been realized could expand the number of individuals who may benefit with minimal additional cost.

The commitment to science does not end with the collection of the last data point or the publication of the last paper. It ends when the participants, as well as the scientific community, understand the impact of the knowledge gained and can incorporate it into their lives.

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