Conceptualizing and testing fidelity-adaptation in the context of developing a digital intervention for depression from an evidence-based in-person format

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Abstract

Background

Digital interventions, such as smartphone apps, have emerged as a promising way to better meet growing population mental health needs. The evidence for many of these digital interventions is currently limited, especially in the context of those adapted from in-person formats. Our team developed a digital depression intervention (VMood) in Vietnam. VMood, adapted from an evidence-based in-person intervention (SSM) developed in Canada, uses cognitive behaviour therapy (CBT) principles with remote coaching by non-specialist providers.

Fidelity-adaptation is a major tension in implementation science. Fidelity is the degree an intervention is delivered as intended. Conversely, adaptations are sometimes made to address specific contexts. This paper aims to identify key elements of fidelity-adaptation – the degree VMood is consistent with the theoretical aspects of the SSM intervention and practical aspects of implementing digitally in the Vietnamese setting.

Methods

This study uses Dimensions from Dane and Schneider's Implementation Fidelity Evaluation Framework: adherence (D1), quality (D2), participant responsiveness (D3), and program differentiation (D4). Discourse data from team meetings explored elements that must remain intact (D1) and those requiring adaptation to fit the digital modus and local cultural context (D4). Non-specialist providers with SSM knowledge and app users from Vietnam tested VMood. Experts familiar with CBT from Vietnam and Canada provided theoretical feedback. Interviews or focus groups were conducted with all participants to gain insights into (D1-4). All qualitative data were analyzed using thematic content analysis.

Results

Key findings were: Adherence (D1): participants agreed that VMood captures the important theoretical content from SSM, with the same content being delivered in a different format and Program Differentiation (D4): participants presented a variety of adaptation suggestions unique for the digital format to strengthen VMood's acceptability, including keeping the app simple by reducing the amount of text; incorporating more dynamic content (e.g., animations, videos) to increase engagement; and including more culturally appropriate scenarios.

Conclusions

The updated VMood intervention is currently being implemented in a randomized controlled trial across eight provinces in Vietnam. With the global increase in digital health services adapted from in-person delivery, understanding how to balance fidelity with necessary adaptations is important both theoretically and practically.

Introduction

Worldwide, one in two people will develop a mental disorder by the age of 75.(1) Improving access to mental health care is thus a critical global priority. This is especially pertinent in low- and middle-income countries like Vietnam, where care is unavailable for 83% of the population who need it.(2) The urgency to reduce the treatment gap has been illuminated within the context of the COVID-19 pandemic, which has led to increases in mental health conditions, including 28% for major depressive disorders and 26% for anxiety disorders,(3) the two most common mental disorders. (4) Currently, more than 300 million people are affected by these disorders.(5) Digital interventions, including smartphone apps, have emerged as a promising and scalable way to better meet population needs given the persistent severe shortage of mental health resources and additional constraints on already limited in-person care imposed by the COVID-19 pandemic. The evidence for many of these digital interventions is, however, limited, especially in the context of those adapted from in-person evidence-based formats.(6)

One of the major debates in implementation science is the tension between fidelity and adaptation of evidence-based interventions for delivery in routine practice.(7,8) Implementation science is the study of methods that facilitate the uptake of evidence-based practices and findings into real-world settings to improve the effectiveness and quality of health services.(9) A key element in implementation science is fidelity, which is the degree an intervention is delivered as intended.(10) Conversely, adaptation is where implementers or users make changes to the initial design of an intervention.(11) The pro-fidelity camp (often program developers) advocate for close adherence to the original intervention, while others in the pro-adaptation camp (often program providers) argue adaptations are necessary to address specific contexts, with particular regards to ensuring cultural appropriateness.(12,13) In the context of digital interventions developed from in-person formats, pro-adaptation adherents also point to features unique to a digital format (e.g., video, animations) that may improve the intervention without straying from its theoretical principles. Developers understand the critical components that must be kept intact, whereas providers are met with practical real-world concerns of failure to implement without adaptations to fit the local context and culture.(13) Influencing factors include time constraints, availability of resources, and community norms.(7) Further, digital interventions are by nature different from in-person interventions, so adaptations may go beyond simple fit with the local context and seek to enhance the intervention itself.

Further Context

There are various challenges to defining and conceptualizing fidelity and associated adaptations in general, including the use of inconsistent terminology. Various terms have been used to describe implementation fidelity, including intervention integrity, treatment integrity, reliability, compliance, and adherence.(20,22) Similarly, adaptations have also been described as modifications and tailoring. A lack of consensus on terminology contributes to further complication in inconsistencies in methods, reporting standards, and operationalization of the concepts.(22–24) There has also been limited attention to methods for adaptations across contexts to ensure cultural appropriateness for relevance, applicability, and ultimately their effectiveness.(25,26) Cultural adaptation can be defined as "the process of systematically modifying an evidence-based intervention to be congruent with the language, values, beliefs, and context corresponding to clients' cultural backgrounds."(13) Suggestions for improving cultural appropriateness include integrating culturally relevant graphics and phrases,(27) and helping to better illustrate different emotional expression, identities, values, and experiences.(26,28)

Conceptualizing fidelity is further complicated in the context of modifying in-person interventions to digital formats, where there is limited evidence on the unique considerations and practical guidance for these adaptations as many of the available adaptation frameworks were developed for face-to-face interventions.(26) In this context, there is a need to evaluate if, and how, the technical and theoretical intervention components are applied in the new mode, or enhanced by drawing on the unique features of a digital format (e.g., videos, animations) to increase interactiveness and engagement with the digital format. Digital interventions support a structure that allows the use of evidence-based strategies to be delivered with fidelity while adapted as long as critical components are kept intact to ensure efficacy.(29)

Research shows that the shortage of mental health professionals and other related mental health services will persist into at least the next decade.(15) Digital innovations for mental health are thus one of the most promising ways to provide accessible and scalable mental health services to the growing population of those who need it, especially for those who encounter additional challenges to face-to-face care, including geographic barriers, challenges imposed by stigma, and safety concerns for face-to-face interactions amidst the COVID-19 pandemic. Digital mental health interventions adapted from evidence-based in-person interventions show further promise to provide scalable and effective mental health care. As treatment fidelity inconsistencies have been identified as a key contributor to the mixed evidence on the effectiveness of many of the digital mental health interventions,(30) there is a need to adopt a definition of fidelity in the context of adapting digital interventions from in-person formats and evaluate fidelity when developing digital mental health interventions.

This Study

Based on a review of the literature, this study will utilize Dusenbury et al.,'s(7) definition of implementation fidelity that encompasses five aspects: 1) strict adherence to methods or implementation that conforms to theoretical guidelines; 2) completeness and dosage of implementation; 3) the quality of program delivery; 4) the degree to which participants are engaged; and 5) program differentiation, or the degree to which elements that would distinguish one type of program from another are present or absent. This definition was chosen as it is comprehensive, capturing both fidelity and adaptation and the perspecives of the intervention recipients through participant engagement.

Despite the recent proliferation of digital health interventions,(14) there is a paucity of evidence on the unique considerations and practical guidance for fidelity of adaptations from evidence-based in-person interventions to digital formats. In this context, there is a need to evaluate if and how the technical and theoretical intervention components are applied in the new mode, while maintaining or enhancing its effectiveness.(11) Our study will contribute knowledge to the literature on fidelity by seeking to both enhance fidelity for the VMood intervention, and conceptualize fidelity in the context of adapting an in-person intervention to a digital format. Further, our study aims to elucidate adapted elements of the intervention to fit local culture and context. Adaptations may help increase scalability, or reach, of the intervention.(15) Lastly, the involvement of stakeholders in decision-making using an integrated knowledge translation approach ensures any necessary adaptations reflect local context while safeguarding fidelity.(13)

Goal of This Study

This paper aims to contribute to the field of implementation science by conceptualizing and identifying key elements of fidelity when adapting an in-person depression intervention to a digital format. This paper is based on a feasibility study that included the testing of a smartphone depression app (VMood) that was developed from an evidence-based in-person intervention, in Vietnam.(16)

Specific interconnected objectives are:

1. Conceptualizing and defining what fidelity means in this specific context (across modes and cultures);
2. Identifying key elements advocated by participants along the fidelity-adaptation continuum.

Methods

Prior and Ongoing Work

Our research team secured funding from the Canadian Institutes of Health Research (CIHR) and Grand Challenges Canada (GCC), with matched funding from the Vietnamese Ministry of Labour, Invalids and Social Affairs (MOLISA) to develop and implement a digital intervention for

depression (*VMood)* in Vietnam. *VMood* is developed from an in-person supported self-management (SSM) intervention initially developed in Canada.(17) SSM is a modified approach to psychotherapy, where elements of Cognitive Behavioural Therapy (CBT) are delivered using a supported self-management approach consisting of an Antidepressant Skills Workbook (ASW) and supportive coaching by a non-specialist provider.(16,17) SSM was shown to be appropriate and feasible in the Vietnamese context in a feasibility study (2014–2015)(18) and was subsequently shown to be effective in Vietnam through a randomized controlled trial (RCT; MAC-FI [Mental Health in Adults and Children – Frugal Innovations Project]; 2016–2019).(16)

SSM has since been adapted for use in Vietnam via a smartphone app by the same research team. The VMood intervention is comprised of 3-months' engagement with the *VMood* program, which includes modules from the ASW introducing depression and antidepressant skills (reactivating your life, thinking realistically, and solving problems) delivered in an interactive format with multiple choice options. Introductory videos with a text option introduce each module, and participants have the option of navigating between the modules. The app sends reminders through push notifications if there is inactivity for a week. The VMood program also includes support on app navigation and basic depression provided remotely through the app by a MOLISA Social Worker. Social Workers provide support as part of their regular job responsibilities and have received training on basic depression, providing coaching via the app, and emergency and suicide management through an online training program developed by the Institute of Population, Health and Development (PHAD). PHAD is a leading non-profit technological and scientific organization in Vietnam and the team's implementing partner.

The results of the feasibility study will form the foundation of further work, conducted via an RCT in eight provinces of Vietnam to test the effectiveness and cost-effectiveness of VMood(19) by establishing key elements of fidelity – in this case the degree to which the new digital intervention is consistent with the theoretical and practical aspects of the in-person intervention to ensure feasibility and usability. Fidelity is critical to establishing internal validity to ensure effectiveness and integrity of the intervention and supports replicability and generalizability. Dunst et al.,(20) have further differentiated between theoretical fidelity, which focuses on the actual intervention, and practical fidelity, which focuses on the implementation process.(20) Though there has been an increase in the literature in recent years capturing theoretical fidelity, most of the research has focused on an examination of enhancing fidelity (practical fidelity).(21)

Overview

Our fidelity testing involved three components: 1) conceptualizing fidelity; 2) measuring fidelity; and 3) enhancing fidelity. Fidelity testing, where critical intervention components are identified, is an important first stage for the evaluation of fidelity.(8,31) In contrast, other "adaptive"(31) components are often modified to reflect local cultural translations crucial to successful implementation and should be captured carefully. Led by our implementing partners in Vietnam and working with a local software development company, we began development of the VMood app in 2021. The prototype was shared with team members for their review of fidelity and suggestions for adaptations.

All procedures were approved by the Research Ethics BC Board in Canada [H21-02938] and the Institutional Review Board at PHAD in Vietnam [PHAD-2022/VMOOD-01].

Conceptual Framework

Fidelity was examined according to four of the five dimensions outlined in Dane & Schneider's Implementation Fidelity Evaluation Framework [See Table 1]:(32) *adherence* (D1), *quality of program delivery* (D2), *participant responsiveness* (D3), and *program differentiation* (D4). *Dose*, the fifth dimension, which measures the amount of the intervention delivered (e.g., number of components completed) was not captured in this paper as this fidelity testing study focused on the qualitative insight of the participants. However, preliminary dose data for VMood will be presented elsewhere.(33) Note that definitions are from Dusenbury et al.,(7) but were originally described in Dane and Schneider.(32)

Table 1
Implementation Fidelity Evaluation Framework(32)

Dimensions (D)	Definition	Measures
D1: Adherence	The extent to which implementation of particular activities and methods is consistent with the way the program is designed.	Identifying core components of the SSM intervention (workbook + supportive coaching) Intervention logs by app users and providers Interviews and focus groups
D2: Quality of program delivery	Effectiveness of the intervention at delivering program content	Interviews and focus groups
D3: Participant responsiveness	The extent to which participants, both those receiving and responsible for delivering, are engaged by and involved with the program.	Interviews and focus groups
D4: Program differentiation	The degree to which elements which would distinguish one type of program from another are present or absent.	Identifying adaptive elements of the SSM intervention (workbook + supportive coaching) Interviews and focus groups

Component 1: Conceptualizing Fidelity

An embedded ethnography method was used for this component, where research team members' participation as "embedded researchers"(34) in discussions around fidelity helped to inform its conceptualization within the context of adapting interventions from an in-person to a digital format. The process involved first defining what fidelity means in this specific context, which included a review of the literature on fidelity in general and in this context. The results from this review are provided in the background section. The tension between fidelity and adaptation served as the analytical framework for conceptualizing fidelity.(35)

Next, discussions amongst team members around the app development process and fidelity-adaptations took place through monthly team meetings and various small-group meetings (in-person and online), along with personal communications (emails). A main source of data meeting minutes and field notes from the in-person team meetings held in Hanoi, Vietnam from August 22–25, 2022. Most of the team members (from Canada, Australia, and Vietnam) attended. The main purpose of the meetings was to officially launch the project in Vietnam, with a substantial portion of the discussion focusing on a workshop examining the app development process, including identifying critically important components of the in-person intervention that needed to be transferred over intact to the app format (D1: adherence) and elements that could be adapted for an app format (D4: program differentiation). The team systematically reviewed a fidelity checklist of critical elements identified prior to the meetings (App Adaptation Fidelity Checklist – see Appendix A). Items were rated as definitely present, somewhat present, or absent. All participating team members reached consensus about the rating categories and then proceeded to rate the critical components of the workbook, discussing the best ways to incorporate the elements. Meetings were also held with the local app development company to communicate decisions.

All discourse data were either transcribed or captured through detailed meeting minutes and field notes summarizing and interpreting the discussions. A main output in embedded ethnography is that the embedded researcher provides formative recommendations arising from the analytical framework.(35)

Component 2: Measuring Fidelity

The second and third components involved experts familiar with CBT principles (n = 2), along with providers involved in implementation of the VMood intervention (n = 15), including two Social Workers based at the provincial Social Protection Centre (SPC)[1] who provided administrative support, and a Policy Stakeholder at the SPC, reviewing the app for theoretical and practical considerations. This took place across six communes (municipal subdivisions) in one district of one province (Thanh Hoa) in Vietnam. Names of the communes and district have been omitted for confidentiality purposes. The communes were selected in collaboration with MOLISA to represent diversity in terms of economic status (e.g., urban/rural; poorer/richer) and population composition (e.g., men/women; elderly/young). Fidelity testing also involved experts (n = 3) from one city (Vancouver) of one province (British Columbia) in Canada.

Participants were asked to review the ASW and the previous RCT (MAC-FI Study) protocol(16) to familiarize themselves with the in-person SSM intervention. They were subsequently asked to review the app for fidelity comparisons with the in-person intervention (D1). Informed by a typology of adaptations summarized by Perez et al.,(11) participants were asked to document their thoughts on: 1) additions or new components; 2) deletions or radical modifications to the intervention components that make the app significantly different to the original in-person intervention; 3) minor or major modifications to an existing component. The purpose of this process was to help participants to systematically track their thoughts on the impact of any adaptations to the intervention (D4), which were explored through qualitative exit interviews in the third component, enhancing fidelity. Additionally, all experts were asked questions assessing cultural fidelity of the app to ensure relevance to the local context.

Component 3: Enhancing Fidelity

The third component involved qualitative exit interviews with the experts (n = 5), Policy Stakeholder, and the two Social Workers based at the SPC, along with focus group discussions (n = 2) with the remaining 13 providers (Community Women's Union staff, i.e., lay workers who are primarily volunteers active in the community supporting social and health initiatives) to gain insights into quality of delivery (D2) and participant responsiveness (D3), and to identify necessary adaptations (D4). D2 questions addressed the degree to which interactive activities focused attention on required core elements of the app. D3 questions examined the extent to which participants felt they were engaged by and involved in the activities of the app along with their level of satisfaction with the intervention. D4 questions examined whether participants noticed any key changes in the digital format and their opinions on these changes (what they liked, did not like, etc.,). Questions also explored participant logs on program differentiation.

Analysis

Discourse data were recorded and transcribed where applicable. All interviews and focus groups were conducted by first author LC, with the assistance of an interpreter. All interviews and focus groups were recorded, transcribed, and translated to English using forward and backward translation. Translations were completed by a professional translator in Vietnam. Detailed field notes during and after the interviews were recorded by LC to capture thoughts and observations about the interactions that could help inform the data analysis process.(36) All qualitative data were analyzed by LC using thematic content analysis as outlined by Braun & Clarke(37) to identify and analyze common themes across transcripts that capture important meanings and patterns in the data. Thematic analysis is the most commonly used analysis method in qualitative research.(38) A coding framework was developed deductively, informed by the fidelity-adaptation analytical framework,(10) and inductively through analysis of the qualitative data. Coding was a multi-stage process: 1) open coding, where preliminary summary statements were provided for elements discussed in the transcript and formed an initial coding framework; 2) gathering all statements from open coding to collapse into main categories; 3) refinement of categories into themes; and 4) verification through validation of the coding by another research team member involved with the project (senior author JON) in the form of independently reviewing 20% of the transcripts.(38) In addition, analysis of focus group data took into account the group dynamics, captured via the focus group discussions themselves and researcher field notes. Data were coded using NVivo 14 software.(39)

Data triangulation and reflexivity were used to help ensure the trustworthiness of the data analysis and research findings.(40) Triangulation was used to explore congruence and divergence between data sources, thus increasing the rigor of the findings and reflexivity, aided by the detailed field notes and memos made during the qualitative coding process, to ensure trustworthiness of the research findings.(41) The audit trail also includes detailed records of the study's methods and procedures. NVivo 14 software(39) was used for all qualitative analysis.

Results

Component 1: Conceptualizing Fidelity

For this component, the tension identified in the literature review between fidelity and adaptation served as the analytical framework.(35) [9]Key elements are described below.

Adherence

Key themes on Adherence (D1) were: 1) content development and 2) critical elements. The content development process began in 2021, through various Zoom team meetings and app development working group meetings, culminating with the in-person August 2022 meetings in Vietnam. From the initial discussions, the team agreed the "priority is to ensure fidelity; make sure the app is as close to the workbook as possible." As the supported in-person self-management intervention is comprised of the workbook and support provided by a lay health worker, the app's modules reflect the different sections of the Workbook, and the support function is embedded within the app through a chat feature with Social Workers. Therefore, when developing the app, fidelity of the workbook focused on the modules and a separate but related evaluation focused on the support component. As a team member indicated, for the app modules, "basically the content comes from the workbook. We just convert the content from the book." For example, the workbook contains an overview of depression along with different skills modules, each with an introduction. Within smaller app development group meetings, team members agreed that introductions could follow different formats, with the overview module presented in the form of a conversation while the others would be presented by one person explaining the details. The support function, which was identified as a key strength of the in-person intervention,(43) was also emphasized to be of key importance to the digital intervention. However, the format and scope of support would need to be adapted to the new mode of delivery (described below).

Following these initial meetings, the team prioritized an evaluation of fidelity at the August in-person meetings to "ensure that the core aspects and the activities are introduced in the app." Findings from the app development workshop component of the meetings, guided by the App Adaptation Fidelity Checklist (see Appendix A) demonstrated firstly that there was unanimous agreement that "there are core critical elements from the workbook that need to be included in some form." Secondly, results showed the team members agreed that critical elements from the workbook were present in the app. For example, team members indicated that all workbook modules were present and delivered appropriately (i.e., in chunks

on separate pages). They also agreed that “modules should be administered in sequential order,” similar to the workbook,” but should include “an option to skip forwards or backwards” along with a “note in introduction recommending participants to go through sequentially.” And similar to navigating through the paper-based workbook, “participants will also have the option of leaving a module mid-way and coming back to where they left off.”

Further discussions provided some clarity on specific intervention components translated to the digital format, such as if an app user participant expresses suicidal ideation according to item 9 of the embedded Patient Health Questionnaire-9 (PHQ-9; depression screening questionnaire): Over the last two weeks, how often have you been bothered by thoughts that you would be better off dead or of hurting yourself in some way?), the team indicated that someone from their local commune (municipal) health centre will reach out to them for follow-up. In the in-person intervention the lay health provider administering the screening would perform the referral.

Differentiation

The team agreed various changes could be made to suit the new mode of delivery to engage users (e.g., reminders, encouraging messages, videos) without straying from SSM’s theoretical principles and also agreed that there were important aspects of the in-person intervention that could not be replicated and demonstrated in the digital format. This includes the critical social support component of the intervention, which involved social collaborators (lay workers unique to Vietnam) in the original in-person intervention who engaged with people in their homes. Team members also identified important considerations for adaptations to ensure the app fits the local context and culture. Themes pertaining to adaptations for Program Differentiation (D4) were: 1) format (gamification, videos), 2) limitations to a digital format, and 3) culture and language are presented below.

For the first theme around app “format”, the team agreed that this could be “flexible and up for discussion” and provided a number of considerations for the digital format, including that the “workbook needs to be simplified for the app”, “more structure is required to address individuals’ limited attention spans, and “need to make sure the app is engaging for participant retention and participation.” Discussion to address these concerns centred around increasing gamification of the app to help participants “keep track of progress” along with “motivation about setting goals and making progress towards those”. Suggestions included incorporating a progress tracker on the main page using different icons (e.g., logos, stars) mapped onto their profile image indicating progress. In addition, team members proposed the inclusion of positive feedback, such as “pieces that participants have to do in order to unlock new components of the app.” The team agreed that these suggested adaptations retain the original theoretical content while potentially enhancing the efficacy of the intervention by providing additional behavioural activation. This could be particularly beneficial by helping to engage app users with depression who are more likely to experience difficulty with motivation and engaging as a result of their depression. Additional discussions centred around the videos introducing the app modules, with consensus in keeping them slower-paced and short (around two minutes), with text broken into digestible chunks, and making them mandatory to be viewed at least once, when app users first navigate to the modules. In line with these suggestions, minor revisions to revise the app module content for simplicity were proposed, including further dividing the word-heavy content for easier access and additional examples for realistic thinking exercises were suggested by the team, and open-source catchy graphics for the modules to replace those from the workbook (which was developed nearly two decades ago in 2005).

The next theme of “limitations to a digital format” included discussions around the Social Worker support function, providing incentives for app users, and screening challenges. As mentioned earlier, a key strength of the in-person intervention was the role that non-specialist providers (who were mostly volunteers) played in not only delivering the intervention and providing coaching support but also human contact to the participants. VMood will involve MOLISA Social Workers, who will provide virtual support remotely through the app. The team noted that, importantly, there is no method of digital delivery that can achieve equivalence with the in-person intervention. In addition, considering that they are providing support as part of their normal responsibilities, their time will be limited. VMood therefore involves a substantial divergence from the in-person SSM intervention for the coaching support function, with much less support, and support of a very different nature. As a reflection of this, the team discussed extensively and in-depth at the August workshop, in subsequent team and smaller working group meetings, and by email the specific role of Social Workers in the context of maintaining feasibility of scaling up the intervention to the general public should VMood demonstrate effectiveness. Eventually, the team agreed the focus needs to be scalability, that “we’re not promising the best treatment, we’re offering something that will reach a broad audience, and the level of support will be lower, but our reach will be broader to promote mental health, rather than treat mental illness.” The role of the Social Worker will be less involved than that of the non-specialist provider in the in-person intervention, focusing on app navigation and providing only basic support for depression. Their training should also be scalable and sustainable and perhaps delivered online through a succinct training program that is administered centrally by MOLISA. To enhance the Social Worker support component, the team agreed that data would be captured on the duration, frequency, and content of Social Worker support chats with the app users to help shed light on which module(s) app users potentially struggle with so any changes can be made to strengthen the app. An additional consideration put forth by the team is that some of these losses resulting from the replacement of a real person as coach could potentially be, at least partially, mitigated by the behavioural activation enhancements mentioned above. For example, the team indicated that coaching support is supplemented by the instructional videos. Despite these potential enhancements, the human contact and relational aspect of the in-person coaching support is missing in the digital format, though team members also noted that even in the in-person intervention this could have varied greatly from person-to-person.

Further, the in-person SSM intervention was already an adaptation and step-down of traditional fully in-person psychotherapy services, but had still shown effectiveness.

Challenges resulting from the loss of a real person as coach also included additional retention concerns, where team members shared their concerns that up to 90% of participants may be lost over the course of the project. However, as contact information is captured in the app, follow-ups can be done by telephone as necessary and a suggestion was made to perhaps include financial incentives for participants in the RCT to conduct the various required assessments in the form of a survey administered at baseline, and again at 3 and 6 months. For screening of inclusion criterion depression caseness and exclusion criterion psychosis, the in-person intervention involved a lay health worker conducting screening in-person, whereas the digital intervention involves the PHQ-9 being embedded in the app, with app users self-administering, and no comprehensive method for screening those with possible psychosis.

Lastly, “culture and language” was an important theme arising from the discussions. The team unanimously agreed at the August workshop that more culturally appropriate scenarios for the realistic-thinking and problem-solving skills should be included to capture different contexts, such as including more rural examples. Team members indicated that many examples from the original workbook seemed focused on office workers, whereas representation should be broadened to include diversity in occupations, such as factory workers and farmers. Team members also indicated that for scale-up to different regions, attention should be given to important language differences as Vietnam is a multi-ethnic country with language variations across provinces and regions within provinces. Team members reviewed and confirmed with the app development company that an app wireframe would be required to ensure all the components discussed at the workshop are captured and reflected in the revised app.

Components 2 and 3: Measuring and Enhancing Fidelity

Table 2
Summary of Data Sources

Code	Source	Notes
IEX*-01	Interview Expert 1	Vietnam
IEX-02	Interview Expert 2	Vietnam
IEX-03	Interview Expert 3	Canada
IEX-04	Interview Expert 4	Canada
IEX-05	Interview Expert 5	Canada
IPS^-01	Interview Policy Stakeholder 1	Provincial Social Protection Centre (SPC)
IPR^{+}-01	Interview Provider 1	Provincial-level Social Workers based at the SPC
IPR-02	Interview Provider 2	Provincial-level Social Workers based at the SPC
FGPR~-01	Focus Group Provider 1	8 commune-level Community Women’s Union Staff
FGPR-02	Focus Group Provider 2	5 commune-level Community Women’s Union Staff
*IEX = Interview with Expert; ^IPS = Interview with Policy Stakeholder; $^{+}$IPR = Interview with Provider; ~FGPR = Focus Group with Provider		

Similar to component 1 (conceptualizing fidelity), the qualitative data component from component 3 (enhancing fidelity) following component 2 (measuring fidelity) demonstrated the overall fidelity of the app to the original in-person SSM intervention. This is described below. See Table 2 for a summary of the data sources.

Adherence (D1)

The extent to which implementation of particular activities and methods is consistent with the way the program is designed.

This dimension explored the consistency of the theoretical concepts in the adapted VMood digital intervention compared to the in-person intervention. Overall, experts agreed that VMood captures the important theoretical content. As one expert reported:

“In terms of content, I don't see anything…. It's just a different experience. One is reading the workbook and doing the workbook. And the other one is experiencing app. And the feeling is like something is talking to you and guiding you. That is the only thing that I can see the differences here.” (IEX-05)

This expert elaborated “It's very accurate the translation from like English to Vietnamese and then the application from the material to the app. I think it's quite accurate. I don't see any differences… The psychoeducation and different steps and they're all there. Yeah, and also like the problem-solving steps as well.” Another expert echoed this, indicating “all the information in there, I think that its really good.” (IE-04)

Lastly, one expert concluded that “And I think that this is, this is an appropriate tool…. I don’t recommend any changes at all”. Experts were unanimous in their feedback on the theoretical fidelity of VMood and did not express any concerns on missing or inconsistent content compared to the in-person intervention.

Quality of Program Delivery (D2)

Effectiveness of the intervention at delivering program content

When participants were asked their thoughts on the ability of VMood at delivering program content, many participants spoke of the strengths of the app in delivering the theoretical content more effectively. For example, one participant mentioned:

“In my opinion, if we compare the book with the app, I find that using the app is much easier and more effective than reading the book…. This one has the advantage of being easier to understand than the book, which is overly long…. Depressed individuals often don't want to do anything, and they lose interest in the things they used to enjoy, particularly reading books… As a result, using the software will be more advantageous.” (IEX-01)

Another participant spoke more specifically about the strengths of some of the content being delivered by video format in the app, “Regarding the two contents, they are mostly the same; however, one of them (the app) is not solely reading but also has videos to go along with it, so people find it more suited.” (IEX-02) They shared that “after watching videos inside the App several times, I really enjoyed it and shared it with others at my hospital, because many of my co-workers are psychologists or specialize in psychology.” Another participant also spoke of the strengths of the instructional videos at delivering the intervention content, indicating “we will need someone, such as a professional, to interpret the book for us. However, the VMood app has detailed instructional videos, which I thoroughly enjoy watching it. I watched several of these and found them to be quite simple to understand.” (IPS-01)

Participants enjoyed the format the content was presented in and were optimistic about VMood’s acceptability in the community. They appreciated the accessibility of the app and its effectiveness at delivering content that in other contexts could be complicated for app users to understand and apply. However, within the app format participants shared that the necessary theoretical content was both present and delivered effectively.

Participant Responsiveness (D3)

The extent to which participants are engaged by and involved with the program

This dimension was captured mainly by app users sharing their experiences on downloading and navigating the app. One app user spoke about how they engaged with the app:

“Many times in life, you can get furious over something. But now whenever I'm angry and need to calm myself down but I don't know how, then I'd open this (App) and read the question; sometimes I skimmed through it and read it, 5 or 6 phrases or so, and occasionally, when I got to the third sentence, it (app) delved into the specific situation and advised me how to manage it.” (IAU-01)

In response to a question on which features of the VMood app they used, an app user indicated that “It was based on my mood at the time, or if I see a feature that I want to use, mostly it’s to see the question set and the video… Those videos provided me with (useful) information, and also learned more about my mental health.” (IAU-03)

Another app user wished to “thank the software, which, as you can see, is highly functional, supports the issues at hand, and not only reflects on your emotions but also on the others in the community and your specific needs, and it is also close to life.” (IAU-01) This app user mentioned that “On average, I use it [the app] between once per day and twice per day, or in general, the more we use it, the better.” App users were receptive to the app personally as they reported it being useful and shared their support for its use more broadly in the community.

Program Differentiation (D4)

The degree to which elements which would distinguish one type of program from another are present or absent. Identifying adaptive elements.

While there was consensus amongst the experts on the fidelity of core theoretical VMood components to the in-person intervention, participants presented a variety of suggestions that would involve adaptations, or modifications to the app which they felt would strengthen the intervention and increase its acceptability without compromising the core components critical to theoretical fidelity. These suggestions included: gamifying, the importance of keeping the app simple, and technical suggestions to improve app.

Gamification

The first suggestion for program differentiation made by the participants was to incorporate more gamification. This included suggestions on increasing the app’s interactiveness through additions such as reminders, progress bars, and encouragement. One provider from a focus group

mentioned that:

“In many cases, users only use this app when we collaborators [community women’s union staff] demonstrate how to install and use it; after that, despite having this software on their phone, they rarely open it out and use it. As a result, I think that for future efforts, there should be something in the app that catches people's attention and draws them into using it.” (FGPR-01)

Other participants suggested unique and advantageous features for a digital format, including “pop-up notification or message once a month or every other month, similar to a Viettel [phone company] message, or a screen notification” (IAU-03), “variety of games for users to enjoy” (IPS-01), “more pictures” (IEX-04)” or “a form of record to track a user’s app usage. It could be in the form of money/compensation, points, or stickers…. Users, for example, will receive a sticker every time they log into the app, or once a week. This can also be displayed as a point. Furthermore, the total number of points can be turned into any other type of value. This, I believe, will encourage more people to download and use the app.” (IPS-01)

From the app user’s perspective, a participant responded to a question on whether they feel motivated to use the software, “Motivation exists only when there is a purpose. Currently, the software has barely any reminders (notifications), so I sometimes forget about it.” (IAU-04) Therefore a critical element identified by participants is to gamify the app more to increase usability. This importance was highlighted by a provider who emphasized that first and foremost:

“If we want people to be interested in using the app, we must include something of interest for them to try and experience, correct? […] As they use the app more frequently, they are able to benefit from it more, which ultimately supports them in overcoming their problems. I think that should be the objective of the app, and not whether or not it is capable of conveying all the content and information in the book.” (IPS-01)

Participants shared that increased gamification would encourage more app users to initially try the app along with fostering long-term engagement, which is crucial, especially as individuals with depression may be less motivated and require external encouragement. While some of the suggestions are beyond the scope and capability of the VMood app, these are important considerations for future scale-up and long-term sustainability of the app.

The importance of keeping the app simple

Participants spoke also of the importance of keeping the app simple, largely by reducing the amount of content and the amount of text, particularly by avoiding complicated terminology, to increase potential engagement and understanding. One participant mentioned that while the app “is easier to grasp now [compared to the in-person intervention][…] it can still be condensed slightly more, only providing the important principles.” (IEX-01) Although participants emphasized that they enjoyed the videos, which provided them with “useful information, and also learned more about [their] mental health” (IAU-03), a participant also suggested that “the duration of each video should be kept to a minimum, as it is often excessively lengthy, causing viewers to become bored. The video should be concise and to the point so that viewers are less likely to become fatigued.” (IAU-03) Another participant explained that:

“we must keep it (the software) as basic as possible. the language must be simple to grasp; avoid using slang or difficult-to-understand language to avoid people getting tired and not using it (the app). Phrases like delusions, hallucinations, and perceptual abnormalities are exceedingly difficult to understand as they are medical and psychiatric terminology.” (IEX-01)

Unlike the original in-person intervention, where ongoing coaching support was provided by a lay health worker who visited the participants in their homes on a frequent basis, the digital VMood intervention requires simplification to ensure participants navigating the app mostly on their own (with only basic support provided remotely through the app by Social Workers) are able to engage with and digest the content.

Technical suggestions to improve the app

Lastly, there were technical suggestions made by participants to improve the utility of the app. These included “some resource to connect and to realign on [when] there are some errors with the internet or some errors with the app[...] There should be some, I mean like a second resource.” (IEX-05) Many other participants indicated that “the font size is a little small,” (IAU-02) which is problematic in general as people are usually viewing from their small smartphone screen, but particularly problematic for elderly participants or other participants with vision challenges. Lastly, participants indicated that for those who identified as not having depression caseness based on the PHQ-9, the current wait time for an opportunity to retake the PHQ-9 of 14 days is “excessively long […] because a person’s psychology as of today and tomorrow may have changed.” (IAU-04) A number of participants suggested that a shorter timeframe for re-taking the PHQ-9 would be better able to truly capture those experiencing depression symptoms. This suggestion from the app user, however, may not necessarily be in alignment with mental health expert advice.

Discussion

Principal Findings

Results from the fidelity testing of VMood helped to contextualize fidelity in the process of developing a digital intervention in Vietnam from an in-person intervention developed originally in Canada and field tested in Vietnam. It also demonstrated both theoretical fidelity to the original psychological CBT principles, including around the psychoeducation, along with necessary adaptations to fit local culture and enhance efficacy. Discussion from the conceptualizing fidelity component provided a clear framework for defining fidelity and identifying critical elements of the intervention that needed to remain intact along with those that could be adapted in this context. Through team members systematically reviewing and discussing how to translate the various components of the in-person intervention (workbook and supportive coaching) to a digital format, consensus was reached on what constituted practical and theoretical fidelity, along with limitations and mitigation strategies.

Measuring and enhancing fidelity components similarly showed participants were confident that theoretical content from the workbook integral to the in-person intervention's effectiveness were intact in the digital format, albeit in a different form. In fact, many participants expressed their preference for the digital format with the workbook content being delivered via an app as it supported an accessible interface to encourage uptake and engagement, particularly for those who may experience low motivation and willingness to engage, symptoms common in those who have depression. This is consistent with the literature showing that digital interventions increase flexibility for intervention recipients as they can engage when and where convenient and helps to reduce the effects of stigma.(44) Findings may contribute further to the evidence on practical fidelity by providing guidance informing the implementation process, and more importantly findings help to fill a critical gap in the limited literature examining theoretical fidelity by focusing on the intervention itself.(20) In addition, while prior studies have typically focused only on adherence, which does not provide a comprehensive understanding of fidelity,(12,45) this study measured several additional aspects of fidelity (quality of program delivery, participant responsiveness), and importantly program differentiation to ensure fit with the local context, which has been highlighted in previous studies.(26,46)

Participants also shared adaption considerations to strengthen the app, including increasing gamification, emphasizing the importance of keeping the app simple, and providing technical suggestions to improve the app. Gamification, defined by Deterding et al.,(47) as the "use of game design elements in non-game contexts" has received great interest in digital health interventions as a key method for promoting user engagement through extrinsic motivation and increasing an intervention's effects,(48) with levels or progress feedback, points or scoring, and rewards or prizes being commonly reported.(48) Gamification in the context of VMood has potential to increase intervention efficacy by adding an additional behavioural activation. While more commonly applied to interventions for physical fitness and for managing chronic illnesses, gamification has been less common for mental health,(47,49,50) perhaps due to its potential inappropriateness for introducing social comparison and competition.(51,52) Similar to the literature, findings demonstrated that team members and research participants agreed and discussed in considerable detail how gamification of the app, including through the use of progress trackers and rewards, would help increase engagement, and there was no discussion of using the app for social comparison or competition. A more recent systematic review and meta-analysis showed that gamification was not a significant predictor of effectiveness of mental health apps for depressive symptoms,(53) suggesting a more complex relationship. Participants also emphasized keeping the app simple to increase user engagement, or actual use of the app, and is consistent with past research showing that less complex interventions are less difficult to implement with high fidelity compared to complex interventions(54); i.e., intervention complexity influences implementation fidelity.

Participants emphasized the importance of adaptations taking into account the local context and culture. Suggestions were made to increase culturally appropriate examples for specific modules such as realistic thinking involving more scenarios with farmers so participants, especially those in rural Vietnam, where services are severely limited, could better relate. Cultural adaptations to interventions to have more relevance with individuals from ethnic minorities have been shown to have greater efficacy(55) and more favourable health outcomes.(56) Vietnam is a diverse multi-ethnic country with 54 ethnic groups, with the minority of the population (14.6%) from the 53 ethnic minorities.(57) Most of the ethnic minorities are concentrated in mountainous and rural areas,(57) where 65.6% of the Vietnamese population live.(58) Developing and adapting an intervention that will cater to the entire population is challenging, but an intervention that first considers the culture and context of the diverse groups by including necessary cultural adaptations is critical to increasing relevance and appropriateness to those who often have the greatest need.

Participants were unanimous that VMood has theoretical fidelity with the CBT program from the in-person SSM intervention; however, they also recognized a key limitation is that the coaching support component cannot be replicated in the digital format. The importance of human contact in psychotherapy has been discussed extensively in the literature.(59–61) Some mitigation strategies were shared, including gamification and rewards to help offset the losses with replacement of a real person as coach, to support behavioural activation and increase engagement and efficacy. Further, Newman et al.,(62) demonstrated that while therapist-assisted treatments are optimal, interventions with reduced clinician contact have also been shown to be clinically effective (although with reduced effectiveness), with increased cost-effectiveness and reduced intensity. Another study comparing guided self-help with face-to-face treatments for depression and anxiety disorders showed comparable clinical effects.(63) VMood seeks to balance effectiveness with scability and feasibility to better meet growing population mental health needs.

The larger project uses an integrated knowledge translation approach, where knowledge users are engaged throughout the entire research process, to support navigation through some of these challenges identified early on in the full research program.(64) As an example, using an

iterative process, data collected from the fidelity testing was continuously fed back to the project upon completion of the different fidelity components, including this conceptualizing fidelity component. This was done to ensure any necessary modifications to the app and overall study design are addressed in a timely manner.

Limitations

While fidelity testing involved both experts and Social Workers who engaged with both the workbook and the VMood app, the study was not able to recruit participants from the previous MAC-FI study to provide their experience on the actual process of utilizing the intervention. Due to health and safety restrictions imposed by the COVID-19 pandemic, the feasibility study was delayed, resulting in a substantial amount of time elapsing between the previous MAC-FI RCT and the current project. As such, fidelity testing was primarily conceptual and did not involve the practical experience of participants familiar with the in-person intervention and workbook who could share similarities and perceived differences based on their actual experiences. However, psychological skills are conceptual and with the involvement of key experts intimately familiar with CBT principles and with depression in general, combined with practical feedback from the providers who were involved in introducing the intervention to app users, we are confident of VMood's fidelity with the in-person SSM intervention.

In addition, there are related ongoing practical issues with balancing fidelity and adaptations beyond the development of the app. Recently, usability testing of the slightly revised version of the app based on feedback from the fidelity testing was completed with members of the Vietnamese community (with experts, providers, and app users), demonstrating various implementation challenges and facilitators, some of which impact fidelity (results forthcoming). Implementation in real-world settings is different from controlled settings(65) and factors found to impact fidelity-adaptation in this study may not fully apply in the different context. Following the usability testing, our research team is currently conducting an RCT that seeks to thoroughly examine the implementation of VMood in real-world settings.(19)

Conclusions

Fidelity and adaptations are crucial to the development of digital health interventions, but equally important will be an examination of the experience of different app users after they complete screening and navigation through the app. Modifications were made to the final version of the VMood app based on feedback from the participants in the fidelity and usability testing. The team has recently launched the final version of VMood in the RCT to test the effectiveness and cost-effectiveness of VMood across eight provinces in Vietnam. Should findings demonstrate clinical effectiveness, further confidence in the app's integrity will be bolstered by results from this fidelity testing. Establishing fidelity and understanding how to balance fidelity with adaptations to fit the local context and enhance efficacy is important not just for the VMood intervention, but also applies globally with the widespread increase in health interventions adapted from in-person to digital delivery.

Abbreviations

CIHR	Canadian Institutes of Health Research
GCC	Grand Challenges Canada
MOLISA	Ministry of Labour, Invalids and Social Affairs
SSM	Supported Self-Management
CBT	Cognitive Behavioural Therapy
ASW	Antidepressant Skills Workbook
RCT	Randomized Controlled Trial
MAC-FI	Mental Health in Adults and Children – Frugal Innovations Project
PHAD	Institute of Population, Health and Development
SPC	Social Protection Centre
PHQ-9	Patient Health Questionnaire-9

Declarations

Ethics approval and consent to participate

All procedures were approved in Canada by the BC Harmonized Behavioural Ethics Board [H21-02938] and in Vietnam by the PHAD Institutional Research Board [PHAD-2022/VMOOD-01]. Informed consent to participate was obtained from all participants. Research was performed in

accordance with the Declaration of Helsinki.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and analysed during this study are available from the corresponding author on reasonable request.

Competing interests

RWL has received honoraria for ad hoc speaking or advising/consulting, or received research funds, from: Abbvie, Asia-Pacific Economic Cooperation, Bausch, BC Leading Edge Foundation, Brain Canada, Canadian Institutes of Health Research, Canadian Medical Protective Association, Canadian Network for Mood and Anxiety Treatments, Carnot, CB Solutions, Genome BC, Grand Challenges Canada, Healthy Minds Canada, Janssen, Lundbeck, Michael Smith Foundation for Health Research, MITACS, Neurotorium, Ontario Brain Institute, Otsuka, Shanghai Mental Health Center, Unity Health, Vancouver Coastal Health Research Institute, and VGH-UBCH Foundation.

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Authors' contributions

LC: contributed to the design of the study; funding acquisition; conceptualizing; project management; conducted data collection and analysis; led manuscript preparation

JM: contributed to funding acquisition; conceptualizing; writing – review and editing

VCN: contributed to the design of the study; funding acquisition; conceptualizing; project development and implementation; writing – review and editing

HT: contributed to project management and implementation; writing – review and editing

HM: contributed to the design of the study; funding acquisition; conceptualizing; writing – review and editing

RL: contributed to the design of the study; funding acquisition; conceptualizing; writing – review and editing

KH: contributed to the design of the study; funding acquisition; conceptualizing; writing – review and editing

XN: contributed to project management and implementation; writing – review and editing

EK: contributed to conceptualizing; writing – review and editing

JON: contributed to the design of the study; funding acquisition; conceptualizing; supervision; writing - review and editing

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Footnotes

1. Social Protection Centre (SPC): responsible for administration of social services for the local health centres and providers of long term care centres for people with severe mental health conditions. They operate under the jurisdiction of MOLISA.

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