Addressing tobacco smoking and drinking to improve TB treatment outcomes, in South Africa: a feasibility study of the "*ProLife*" programme

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Abstract

Background: Alcohol and tobacco use may lead to negative treatment outcomes in tuberculosis patients, even more so if they are HIV-infected. We developed and tested the feasibility of a complex behavioural intervention ("ProLife") delivered by lay health workers (LHWs) to improve outcomes in tuberculosis patients who smoke and drink alcohol, at nine clinics in South Africa. **Methods:** The intervention comprised three brief motivational interviewing (MI) sessions augmented with a Short-Message Service (SMS) programme, targeting as appropriate: tobacco smoking, harmful or hazardous drinking and medication adherence. Patients received SMS-messages twice a week. We measured recruitment and retention rates and assessed fidelity to the MI sessions. Lastly, we explored LHWs' and patients' experiences through semi-structured interviews. **Results:** We screened 137 TB patients and identified 14 smokers, 13 alcohol drinkers and 18 patients with both behaviours. Participants' mean age was 39.8, and 82.2% were men. Lay health workers did not achieve competency thresholds for technical (2 [Standard deviation, SD 0.8]) and relational (1.9 [SD 0.7]) scores and performed poorly on reflection-to-question ratios (0.4 [SD 0.4]). Yet, most TB patients rated the MI sessions as helpful and ascribed many positive attributes to their counsellors. Patients also reported behavioural changes. Lay health workers believed patients benefited from the intervention. They had a basic grasp of the non-directive approach of MI counselling but struggled to

implement some MI techniques. Despite technical issues, SMS-messages also played a reinforcing and complementary role. **Conclusions:** These preliminary findings support the feasibility of the ProLife programme targeting multiple risk behaviours in TB patients.

Key Words: Tuberculosis, eHealth, Motivational Interviewing, Tobacco cessation, Alcohol use, Medication adherence

Background

South Africa has the highest TB incidence rate out of 30 high TB-burden countries in the world {{874 World Health Organization 2016}}. Successful TB treatment is compromised by high rates of treatment interruption, drug resistance and deaths {{874 WorldHealthOrganization 2016}}. TB patients who are HIV-positive, are at greater risk of dying, but early antiretroviral treatment (ART) initiation greatly reduces this risk {{789 Abdool Karim,S.S. 2011}}. Successful TB treatment can also be compromised by lifestyle behaviours. In particular comorbid tobacco use and problem drinking are common among TB patients {{700 Peltzer,K. 2013; 711 Louwagie,G.M. 2013; 835 Peltzer, Karl 2014}}. Both smoking and alcohol use increase the risk of death and poor treatment adherence for TB patients {{624 Naidoo,P. 2013; 675 Waitt,C.J. 2011}}. Tuberculosis patients who smoke tobacco also have treatment failure more often and are prone to relapse {{814 Leung,C.C. 2015}}. Furthermore, patients who are co-infected with TB and HIV, and who smoke, are predisposed to a myriad of HIV-related complications {{261 van Zyl Smit,R.N. 2010}}. In addition tobacco smoking and alcohol consumption are associated with reduced ART initiation and adherence {{886 Moreno,J.L. 2015; 885 Hendershot,C.S. 2009}}, which also negatively influences clinical response to treatment . There is thus a need to address smoking and drinking in patients with TB and HIV co-infection.

Brief smoking cessation interventions are effective and affordable in low-income countries, both for TB patients and other smokers {{831 West,R. 2015; 818 Louwagie,G.M. 2014; 595 Siddiqi,K. 2013}}. According to the theory of teachable moments, TB patients are more likely to be receptive to interventions and more likely to succeed in quitting smoking and moderating alcohol use, compared to general smokers and problem drinkers {{820 McBride,C.M. 2003}}. Due to the wide-spread comorbidity of TB with communicable and non-communicable diseases, leading scientists have advocated that TB control efforts integrate with general health care services {{812 Jackson-Morris,A. 2015; 819 Marais,B.J. 2013}}, which include treatment for addiction. Addressing smoking and alcohol misuse in TB patients can have distinct short- and medium-term benefits {{261 van Zyl Smit,R.N. 2010; 521 Arcavi,L. 2004}}. For example, TB patients who stop smoking show a reversal of immunological abnormalities within six weeks of cessation and could have a greatly reduced risk of death due to TB. Although many studies have separately evaluated the effectiveness of tobacco cessation, alcohol reduction or adherence interventions in TB patients {{828 Suwankeeree,W. 2014; 868 Shin, Sonya 2013}}, only a few have considered joint interventions for multiple behaviours to improve treatment outcomes {{887 Howard,A.A. 2016; 829 Thiam,S. 2007}}. Yet, it is not uncommon that these behaviours co-exist in the same patient {{835 Peltzer, Karl 2014; 711 Louwagie,G.M. 2013}}.

To our knowledge, no studies have reported on interventions that use Motivational Interviewing (MI), a patient-centred counselling approach, to address multiple behavioural problems that negatively impact TB outcomes. Motivational interviewing is a counselling style that helps patients to explore and resolve ambivalence aimed at changing behaviour {{642 Rollnick S, Miller WR 1995}}. This counselling technique

has been effectively used to reduce hazardous drinking, affect tobacco cessation, and improve TB treatment or ART adherence {{888 Kahwati,L. 2016; 818 Louwagie,G.M. 2014; 809 Golin,C.E. 2006; 420 Rubak,S. 2005}}. Motivational interviewing can be adapted for use in busy clinical practices {{493 Rollnick,S. 1997}} and even single session interventions have been successfully used by lay health workers (LHWs) to effect behaviour change {{818 Louwagie,G.M. 2014}}. Mobile phone technology using SMS messages can also enhance ART adherence and smoking cessation interventions {{880 Hirsch-Moverman,Y. 2017; 870 Free, Caroline 2013}} and potentially promote adherence to TB treatment {{822 Nglazi,M.D. 2013}}.

Given the potential benefits of MI and SMS-messages to reduce smoking and alcohol use by TB patients, we designed the “ProLife” programme. This programme aims to “Improve TB outcomes by modifying life-style behaviours through a brief motivational intervention and SMS-programme”. We tested the feasibility of this programme in a group of TB patients that used tobacco, drank alcohol or did both. We monitored fidelity to MI sessions, and assessed the proficiency of healthcare workers facilitating the MI sessions. We used semi-structured interviews to evaluate the experiences of TB patients and LHWs. We also determined enrolment and follow-up rates of TB patients.

Methods

Design

We used the Medical Research Council guidelines for developing and evaluating a complex intervention {{876 Craig,P. 2008}}. First we developed an appropriate conceptual framework based on existing evidence of behavioural factors that influence TB treatment outcomes (Figure 1). We used mixed methods to determine

the intervention fidelity, acceptability and likely enrolment and retention rates of the future trial.

Insert Figure 1 here

Study setting

This study was conducted in one health district in each of three South African provinces (Free State, Gauteng and North West), in three clinics per district.

Study participants

TB patients were adults who initiated TB treatment, or who had been on treatment for less than one month for the current TB episode for bacteriologically or clinically confirmed drug sensitive pulmonary TB (PTB) {{900 TB DOTS Strategy Coordination, National Department of Health South Africa 2014}}. Eligible patients included current smokers, defined as having smoked any tobacco in the past month and hazardous or harmful drinkers. We identified hazardous drinkers according to the Alcohol Use Disorders Identification Test [AUDIT] score ≥ 8 for men or ≥ 7 for women and < 16 for hazardous drinking and between 16 and 19 for harmful drinking {{897 Babor T.F., Higgins-Biddle J.C., Saunders J.B., Monteiro M.G. 2001}}. Patients who smoked and drank alcohol were also enrolled. We did not enrol dependent drinkers but referred them for specialist treatment and intensive intervention. However, we retained patients who were both alcohol dependent (AUDIT >19) and smoked because their smoking could be amenable to the MI intervention. We excluded patients who did not possess a functioning cell phone, were too ill to be interviewed or who did not speak any of the languages used in the exit questionnaires (English, Isizulu, Sesotho and Setswana).

To measure fidelity to the MI counselling intervention, we randomly sampled one patient enrolled between 15 November 2016 and 30 February 2017 for each LHW. If a selected patient did not have three recordings, we selected the next available patient.

Lay health workers delivered the intervention and participated in exit interviews. The criteria used to select LHWs are described in the following section.

The ProLife intervention programme package

Brief Motivational Interviewing (MI)

In MI, the counsellor helps the client to explore motivation and confidence to change harmful behaviours and, helps the client to identify suitable ways to deal with obstacles to behavioural change {{642 Rollnick S, Miller WR 1995}}. The five guiding principles of MI are (a) expressing empathy, (b) developing discrepancy, (c) avoiding argumentation, (d) rolling with resistance, and (e) supporting self-efficacy {{838 Miller, WR 1991}}. We opted for the brief MI approach {{493 Rollnick,S. 1997}} as the programme had to be feasible in the resource constrained environments of busy TB clinics in South Africa, and other low and middle-income countries.

We selected nine LHWs to deliver the brief MI intervention. Eligible LHWs were not currently employed as LHWs, had completed high school, completed the nationally prescribed 56 days training for LHWs and had at least one year of previous relevant HIV- or TB-related counselling experience.

During an expert review workshop, we compiled background information on tobacco cessation, problem drinking and factors that influence adherence and agreed on the framework of the MI counselling intervention. An experienced, certified MI facilitator then developed a detailed training manual in collaboration with the experts and

trained the LHWs in a five day workshop. In the first intervention session - at the start of TB treatment, LHWs established rapport and determined the participant's tobacco smoking, problem drinking and other potential obstacles and facilitators for treatment adherence. With the support of the LHW the patient then identified his/her priority problem for change (namely alcohol, tobacco or medication adherence), thus setting the agenda for change. This agenda for change could include a plan to quit tobacco smoking, reduce drinking or deal with other perceived obstacles relating to treatment adherence or initiation. The second MI session built on the previous session and dealt with challenges relating to the previously set agenda, and then moved on to the next behavioural problem. The third session either dealt with the final identified problem or reinforced the previous message. The one-to-one counselling sessions were reinforced by SMS-messages, supporting tobacco cessation, alcohol use and medication adherence. The SMS-stream was automatically initiated one day after the first MI session and was delivered twice a week for up to 12 weeks (Figure 2).

Insert Figure 2 here

SMS-programme

For tobacco cessation and TB-related messages, we selected and adapted messages from an SMS-bank developed by the World Health Organisation as part of their "Be He@lthy Be Mobile programme" {{899 World Health Organization and International Telecommunications Union 2014}}. The research team developed alcohol-related messages during an expert workshop. We based the content of the SMS-messages on the Information-Motivation-Behaviour Skills programme as adapted for TB {{810 Iribarren,S.J. 2014; 896 Fisher,J.D. 2006}}. For example, to target smoking cessation, we sent the message "Within 1 month of quitting, you will cough less and breathe easily" to provide information and motivate the participant to

quit. We provided tools and tips to support adherence behaviour by sending messages such as “Take your TB medicines always at the same time, like when you brush your teeth. That will help you remember”.

Professional translators translated SMS-messages into the three most common local languages and formatted the messages to comply with SMS character limitations. Study patients received 10 TB-related messages followed by seven alcohol reduction- and/or seven cessation-related messages, as appropriate.

Measurements and data collection

Between 15 November 2016 and 30 March 2017, fieldworkers identified eligible TB patients at respective TB clinics, using a screening questionnaire and scheduled three MI sessions: at enrolment, at one month- and at two-month follow-up. All reasonable attempts were made to schedule the appointments for MI counselling on the same day as appointments for TB treatment. Patients also received SMS-reminders of planned and missed visits. Furthermore, district coordinators and fieldworkers who were not involved with patient counselling contacted patients when needed. MI sessions were audio-recorded for later assessment of treatment fidelity.

After their third MI session, district study coordinators administered a semi-structured questionnaire to TB patients, in their preferred language, to determine their experiences with the counselling, the counsellors and the SMS-programme. The patient questionnaire was developed specifically for this study and consisted of structured questions with binary or Likert-type response options.

Each LHW was interviewed using an open question format after they had completed counselling sessions for at least three TB patients, where possible. The interviews covered the following topics: LHWs’ experiences with MI delivery, their perceptions

regarding the SMS-programme, the perceived impacts of MI on the patients, and their overall experiences with the “ProLife” project. The interviews were conducted by a trained Master’s student (L.P), audio-recorded and translated into English

Data management and analysis

Quantitative data from the semi-structured questionnaires with TB patients were analysed with Stata Statistical package version 14 {{609 Stata Corporation 2015}}. Data were descriptively analysed with percentages, means and standard deviation or medians and interquartile ranges, as appropriate.

Qualitative data from the exit interviews with LHWs were transcribed, translated, coded and thematically analysed by two researchers who independently identified themes and compared results. We verified the quality of the transcriptions by listening to the tapes and comparing them to the written transcripts.

Counselling sessions were audio-recorded, transcribed, translated and coded independently by two researchers and average scores calculated. To score MI fidelity, coders listened directly to the audio-recordings in the original language and read through the transcribed and translated transcripts. The fidelity of the MI intervention was determined with the MI Treatment Integrity tool version 4.1 {{901 Moyers,T.B. 2016; 902 Jelsma,J.G. 2015}}. This tool consists of two components viz. global variables and behaviour counts. Counts are determined by simply adding the number of statements that fall in a certain category. The “global ratings” allow the coder to assess how well or poorly the counsellor adheres to the MI practice and can be divided in technical components (cultivating change talk and softening sustain talk) and relational components (partnership and empathy). The “behaviour counts” assess the verbal behaviour of the counsellor during the intervention: giving information, persuade, persuade with permission, questions, simple reflections,

complex reflection, affirm, seeking collaboration, emphasizing autonomy and confront. Summary measures entail the total number of MI adherent (Seeking collaboration, Affirm, Emphasizing Autonomy), total number of MI non-adherent statements (Confront and Persuade), global technical and relational scores, reflection-to-question ratio and percentage complex reflections. Individual and summary scores were calculated for each coder and for both coders together and we determined interrater reliability for the summary measures. The intra-class correlation, using the two-way mixed model with absolute agreement, was used as a measure of interrater reliability for the summary measures.

Ethical considerations

Ethics clearance was obtained from the Ethics committees of Sefako Makgatho Health Sciences University (SMUREC/D/77/2016:IR) and from the other five participating research institutions. Consent was obtained from TB patients for screening and again to participate in the study, including for TB record review and for the audio-taping of the MI sessions; and from LHWs to be interviewed. TB patients received ZAR 60 (about 4 USD) reimbursement for each study visit. The Prolife study was registered in the ISRCTN registry with study ID ISRCTN62728852.

Results

Enrolment and follow-up of study patients

Enrolment and follow-up figures are presented in Figure 3. Out of 141 TB patients approached to participate in the study, four did not consent to screening and 92 were excluded for reasons listed in Figure 3. The most common reason for exclusion was that some patients had already been on TB treatment for more than one month. Only

21 patients were excluded because they did not smoke cigarettes or drink alcohol in excess.

Insert Figure 3 here

Patients were on average 39.8 years old (SD 13.3) and most were male (82.2%). Nearly one third of the patients were eligible because of exclusively drinking (28.9%), 31.1% because of exclusively smoking and 40.0% for concurrently drinking and smoking. Nearly all patients (93.3%) received their first MI counselling session, but close to 30% failed to receive their second or third MI session due to various reasons (Fig 3). Two patients died during the course of the study: one patient between the baseline and one month follow-up and one between one and two months follow-up (Fig 3). The causes of death were unrelated to the study intervention.

Motivational interviewing fidelity

We analysed the fidelity of 22 MI sessions. Two recordings (one for two different counsellors each) were not audible, for two sessions the patient did not give permission to record and one recording could not be retrieved. The complete recorded sessions lasted from 5–26 minutes with an average of 18 minutes (SD 5.8). The MITI tool recommends that a section of 20 minutes is analysed to determine the fidelity. Where the session was shorter than 20 minutes, the entire session was analysed.

In terms of the global counts, a significant number of the LHWs' counselling sessions were considered to be below proficiency levels on cultivating change talk and on partnership (mean score below 2). Scores were however considerably better for softening sustain talk. The LHWs counselling sessions were judged not to have achieved the basic proficiency threshold of 3.5 for relational mean scores

(partnership + empathy). The technical mean score (cultivating change talk + softening sustain talk) was also below the treshold of 3 for both coders. However the interquartile range (IQR) suggests a wide variation in the quality of the recorded MI sessions delivered by the LHWs with the upper quarter of the IQR reaching close to proficiency levels (Table 1).

For behavioural counts “asking questions” had the highest mean score of more than 16 for both coders, followed by simple reflection with a mean score of five. The counsellors did not perform well on the following: giving information, complex reflection and seeking collaboration (Table 1). Only one counsellor had three complex reflections in a session. The overall percentage complex reflections threshold of 40% was not reached. The counsellors asked mostly closed questions. The ratio of reflections to questions was 1:2. They did not meet the fair or good competency and proficiency ratio of 1:1 and 2:1 respectively. Lay health workers made on average 5.5 MI adherent (affirm, emphasize autonomy and seek collaboration) and 3.3 non-adherent statements or interventions (confront and persuade) The threshold of the “MI adherent” and “MI non-adherent” was left unspecified due to a lack of supporting guidelines {{901 Moyers,T.B. 2016}}.

Other problems identified from the MI recordings were that LHWs struggled to set the agenda at the beginning of the sessions and evoke change talk. Some of the LHWs dealt with three target goals (smoking, alcohol and medication adherence) all at once and were unable to focus and direct the session effectively. Furthermore, many LHWs struggled with to use the “ruler” on which patients were asked to indicate their motivation or confidence to change, on a 10-point scale.

The interrater reliability of the two MI Treatment Integrity coders over all three sessions was in the excellent range for the total number of MI adherent (Intracluster

Correlation Coefficient [ICC]: 0.96) and MI non-adherent behaviors (ICC: 0.97). The interrater reliability was moderate for relational scores (ICC 0.67) and good for technical scores (ICC 0.82) (Table 1).

Insert Table 1 here

Satisfaction with the MI counselling intervention: TB patients' perspectives

Although 29 patients were interviewed, data were missing for four patients for whom electronically captured data did not synchronise at the data server. Most patients rated the intervention sessions as helpful or very helpful. All patients enjoyed the sessions "quite a lot" or "a great deal". About half of the patients self-reported reduced smoking and drinking. Most patients reported feeling better emotionally and physically and better adherence to TB treatment. All patients liked the counsellors' style of interacting "a lot" and patients ascribed many positive attributes to the counsellors while rarely endorsing any listed negative attributes (Table 2). Response to open questions supported the trends from the closed questions. None of the patients reported challenges with the counsellors.

Insert Table 2 here

Satisfaction with the MI counselling intervention: LHWs' perspectives

Delivery of Motivational Interviewing

Lay health workers seemed to have a basic grasp of the non-directive approach of the MI counseling style and felt they were able to implement some, but not all, MI techniques quite effectively. For example, one LHW described her experience of the MI approach as follows:

"The things I was able to do even after training were open-ended questions, affirmation, reflecting and making a summary of what the client is telling me, but the problem is I could not put them in order."

Lay health workers reported being less certain about how to implement specific MI counseling techniques and were not clear about where and when during the sessions certain tools, such as the confidence scale, should be employed. Another common challenge was not knowing how to deal with patients who denied using tobacco or alcohol.

Lay health workers felt positive overall about the training received but also felt that they were unprepared for the diversity of problems, attitudes and beliefs that patients presented with in the clinics. They felt that they needed additional practice to enable them to more confidently implement the MI intervention. The following quote is illustrative:

"…everything was done well in the training, because at the training it's simple to answer questions and now when it comes to the counseling it's a challenge because you get different clients depending on their problems, so if you practice more it could help, (...)"

Perceived impact of the "ProLife" Programme

The LHWs reported numerous ways in which they believed patients benefited from being in the programme. They reported observing improvements in patients' general physical and mental health, their TB, and also their increased knowledge, motivation to change and actual change in drinking and tobacco smoking behavior. The following quotes exemplify this observation:

"The first patient, like he was literally crying, and he explained to me that he has difficulty because he lives alone and feels lonely and is suicidal, so he felt if the programme gets terminated there won't be anyone who will listen to him. So I think MI has a big impact on people's lives, (…). Like he was happy as if I did something and all I did was sit and acknowledge him. (…) so people really need MI because there is no one who talks to them at home, (...)."

SMS-programme: TB patients' perspectives

TB patients' experience with SMS-messages was positive overall. Some patients struggled to understand some messages, had technical problems with their phone or with the SMS-delivery. For example, some patients received many messages at once or none at all. However, most patients indicated that they would have liked to receive messages for a longer time period (Table 3).

Insert table 3 here.

In response to open questions, patients indicated that the SMS-messages encouraged them to change their smoking and drinking behaviour and to maintain any changes they had made. SMS messages were useful reminders for taking TB medication, and provided patients with new information about TB. In general, patients did not seem to experience problems while receiving SMS messages with other people around and in fact seem to have triggered some social support as illustrated by the quote below:

"I was able to read the SMS and educate my friends about TB, some of my friends wanted to come with me today (…)"

SMS-programme: LHWs' perspectives

Lay health workers viewed the SMS-messages positively. They felt that the SMS-messages complemented the "ProLife" programme in a number of ways. The SMSs reminded patients about the facts and information imparted and behavior change(s) agreed upon.

"According to me I think they (MI and SMS) are both important because patients are happy that we talk to them verbally and again send SMSs that remind them of the important comments"

Lay health workers felt that the SMS-messages might not be suitable for patients who do not own phones or had to rely on others to access their messages.

Overall experience and satisfaction with the "ProLife" intervention

TB patients were satisfied with the programme and expressed happiness in participating, but also mentioned a few shortcomings of the intervention. For example, several patients did not like the counselling sessions being recorded. Lay health workers also felt that the tape recorders hindered free participation by some of the patients.

The LHWs' experiences regarding patients' attendance at the initial and follow-up counseling sessions varied considerably. While some patients arrived on time for their counseling appointment, others were not so punctual.

"The things I liked are that the patients were happy. Most of them were on time for the session, and they would come when we were busy recruiting (…) just to pass their greetings. They would be happy just to see that there are people who care and want to see them cured and feeling good."

The LHWs were very positive about their experiences in the project as a whole. One LHW described her feelings as follows:

> *"I like knowing about the new counseling programme. It helped me not only to help people who are sick but in life in general, (…). Also the fact that I was making a difference in people's lives, like sometimes nurses shout at them (patients) and when they think of going back to the clinic to come across the rude nurse again they rather stay home, (…)."*

All the participants felt that there is widespread need for a "ProLife" intervention. The main challenges for LHWs were limited space and privacy for sessions in the clinics. Lay health workers were also concerned about the well-being of very ill patients and becoming infected with TB in TB clinic settings.

Discussion

This study's findings are in support of the relevance of addressing smoking and drinking in TB patients and of the feasibility of using lay health workers to deliver a complex behavioural intervention. Both tobacco smoking and problem drinking were common in newly diagnosed TB male patients with more than a third of the enrolled patients concurrently smoking and drinking alcohol. This extent of clustering of behaviours is consistent with findings in the published literature {{892 Schuit,A.J. 2002}}. Recent evidence suggests that multiple risk behaviour interventions similar to the "ProLife" programme, can be effective and that sequentially address smoking alongside other interventions as used in ProLife is preferable to simultaneous interventions {{894 Meader,N. 2017}}.

Even though MI was positively received, LHWs were not fully confident with using all of the specific techniques and tools and did not achieve the desired MI proficiency. One of the possible explanations is that thresholds recommended in the MITI 4.2 guidelines are designed for full-length MI sessions. Specified thresholds may therefore not be appropriate for brief MI sessions in which there would naturally be fewer behavioural counts and fewer opportunities for reflections. The context in which the MI took place, namely at a teachable moment should also be taken into account. This could explain the low change talk counts versus the high sustain talk counts. Nevertheless, LHWs often assumed an expert role thus leading to low scores for the "partnership" attribute. In struggling to transition their practice from the traditional counselling to the MI style, LHWs often tended to provide information without asking permission, directing patients on what to do and seldom letting the patients decide what measures they needed to take to achieve the desired change. The findings are consistent with those from another South African study which also reported low competency of lay counselors in delivering MI despite five days of training {{745 Dewing,S. 2013}}. Lay health workers require extended practice and follow-up support to ensure that they are completely competent in MI delivery {{762 Madson,M.B. 2009; 745 Dewing,S. 2013}}.

Although the South African National TB treatment guidelines clearly stipulate the need for counselling TB patients on tobacco smoking and drinking {{900 TB DOTS Strategy Coordination, National Department of Health South Africa 2014}}, it is not clear whether these guidelines have been adhered to or are adopted. Several TB patients stated explicitly that they felt listened to and "heard" for the first time in the "ProLife" MI counselling sessions. Patients said that the MI sessions motivated them to adhere to their TB/HIV treatment and encouraged them to reduce their drinking

and smoking. Similarly, LHWs, who all had prior training and experience with counselling, reported having learnt completely new techniques, such as simple listening or showing empathy, and expressed surprise at their effectiveness as a communication strategy. Motivational interviewing seemed to vary from the often paternalistic counselling styles traditionally adopted in South Africa {{747 Dewing,S. 2013}}[55]. The positive reception of MI by LHWs and patients combined with existing evidence of the effectiveness of MI {{888 Kahwati,L. 2016; 818 Louwagie,G.M. 2014; 809 Golin,C.E. 2006; 420 Rubak,S. 2005}} are encouraging reasons to test this intervention in a more definite trial.

For the definite trial that followed this study, we provided four days additional MI training with specific emphasis on shortcomings identified during the feasibility study. Contextual challenges, such as lack of space and privacy in clinics, were also addressed.

Similar to the findings of another South African study {{878 Georgette, Nathan 2016}}, patients were overall positive about the SMS-messages. The SMS messages served as important reminders and motivators to sustain behaviour change. Many patients wished to receive the messages for longer. At the same time, some patients indicated that the message were difficult to understand. We have since revised the translation. In the era of information technology, the World Health Organisation has recommended digital health as one of the strategies to help end TB, but highlights the need for more evidence on its effectiveness {{882 World Health Organization 2015}}. This feasibility study and the planned trial will aid in providing answers regarding the use of the recommended mHealth for patient care.

Our study was limited by the small sample size, but provides evidence for the feasibility of the intervention. Social desirability bias may have led to overly positive

feedback from both LHWs and TB patients': Self-reported reduction in drinking and smoking were not validated. The custom-designed software package for enrolment and follow-up of study participants linked to the delivery of SMS-messages posed some challenges during implementation. In particular, there were challenges with system design and with poor data synchronisation often as a result of erratic internet access at some study sites. The SMS-delivery system was reviewed and close monitoring of SMS-delivery is currently performed in the roll-out of the actual trial. The identified challenges in this study are not unique {{879 Adeloye, Davies 2017}} and serve as helpful guidance for other researchers and policy makers who plan to introduce digital health interventions in similar settings.

Conclusions

In summary, this study indicated that implementation of the ProLife programme is feasible within TB clinics and acceptable to TB patients. The moderate to high follow-up rates suggest that patients will follow through and demonstrate potential for sustained involvement in future intervention trials. The approach of enhancing MI with SMS-messages was welcomed by the patients and LHWs. The LHWs were also well received by the patients but they will need extended practice to handle the complexity of MI as a counselling style.

References

Table 1. MI Treatment Fidelity of lay health workers delivering counselling sessions

	1st coder (N=22)		2nd coder (N=22)		Average both coders (N=22)	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Global counts						
Cultivating change talk	1.5 (0.7)	1 (1 – 2)	1.5 (0.7)	1 (1 – 2)	1.5 (0.7)	1 (1 – 2)
Softening sustain talk	2.8 (1.0)	3 (2 – 4)	2.1 (1.0)	2 (1 – 3)	2.4 (1.0)	2.5 (1.5 – 3.0)
Technical[a]	*2.1 (0.8)*	*2.0 (1.5 – 2.5)*	*1.8 (0.7)*	*2 (1 – 2)*	***2.0 (0.8)***	***2.0 (1.5 – 2.5)***
					0.82[g]	
Partnership	1.8 (0.7)	2 (1 – 2)	1.6 (0.7)	1.5 (1.0 – 2.0)	1.7 (0.7)	2 (1 – 2)
Empathy	2.1 (0.8)	2 (2 – 3)	2.0 (0.8)	2 (1 – 3)	2.1 (0.8)	2 (1 – 3)
Relational[b]	*2.0 (0.7)*	*2.0 (1.5 – 2.5)*	*1.8 (0.7)*	*1.5 (1.0 – 2.5)*	***1.9 (0.7)***	***2 (1.3 – 2.5)***
					0.67[g]	
Behavioural counts						
Giving information	0.5 (0.7)	0 (0 – 0)	0.5 (0.8)	0 (0 – 1)	0.5 (0.7)	0 (0 – 1)
Questions	16.1 (6.8)	13 (11 – 19)	16.4 (7.4)	15 (12 – 21)	16.2 (7.0)	14.5 (11.5 – 20.0)
Simple reflection	4.8 (5.3)	3.5 (2.0 – 5.0)	5.0 (5.1)	4.5 (2.0 – 6.0)	4.9 (5.1)	4 (2 – 6)
Complex reflection	0.3 (0.8)	0 (0 – 0)	0.7 (1.1)	0 (0 – 1)	0.5 (1.0)	0 (0 – 1)
Reflection: Question ratio[c]	*0.3 (0.5)*	*0.2 (0.2 – 0.4)*	*0.4 (0.5)*	*0.2 (0.1 – 0.6)*	***0.4 (0.4)***	***0.2 (0.1 – 0.4)***
					0.67[g]	
Complex reflection %[d]	3.3 (8.1)	-	8.6 (13.5)	-	**6.0 (11.4)**	-
Affirm	2.3 (1.6)	2.5 (1.0 – 3.0)	2.0 (1.7)	1.5 (1.0 – 3.0)	2.1 (1.6)	2 (1 – 3)
Emphasize Autonomy	2.4 (2.3)	2 (1 – 3)	2.0 (2.1)	1.5 (1.0 – 3.0)	2.2 (2.2)	2 (1 – 3)
Seek Collaboration	1.0 (1.0)	1 (0 – 2)	1.4 (1.4)	1 (0 – 2)	1.2 (1.2)	1 (0 – 2)
Total MI Adherent[e]	*5.7 (3.7)*	*5.5 (3.0 – 8.0)*	*5.3 (3.9)*	*4.5 (2.0 – 8.0)*	***5.5 (3.7)***	***5.0 (2.5 – 8.0)***
					0.96[g]	
Persuade	2.7 (4.9)	1 (0 – 3)	2.2 (4.4)	1 (0 – 2)	2.5 (4.6)	1 (0 – 2.5)
Confront	0.9 (2.1)	0 (0 – 0)	0.9 (1.9)	0 (0 – 1)	0.9 (2.0)	0 (0 – 1)
Total MI Non – Adherent[f]	*3.6 (6.3)*	*2 (0 – 4)*	*3.1 (5.7)*	*1 (0 – 3)*	***3.3 (6.0)***	***1.5 (0.0 – 3.5)***
					0.97[g]	

[a] Technical count = Average score of cultivating change talk and softening sustain talk, basic competency threshold score=3; [b] Relational count= Average score of partnership and empathy, basic competency threshold score=3.5; [c] Reflection to question ratio = No. reflections/No. questions, fair practice level=1, good practice level=2; [d] Percentage complex reflections = (no. complex reflections/total no. reflections) x 100; [e] MI non-adherent=Sum of confront and Persuade, [f] MI adherent = Sum of seeking collaboration, affirm, emphasizing autonomy; [g] Intraclass correlation coefficient

Table 2. TB patients' experiences and satisfaction with the counselling programme and with the counsellor (N=25)

Variable	n (%)	Variable	n (%)
Rating of intervention sessions		These sessions did not benefit me in any way	0 (0.0)
Very unhelpful/ Somewhat unhelpful[a]	2 (8.0)	Other people would benefit from attending these sessions	11 (44.0)
Helpful	16 (64.0))	Likes the counsellor's style of interacting:	
Somewhat helpful/Very helpful[a]	7 (28.0)	Not at all/A little[a]	0 (0.0)
Enjoyment of intervention sessions		Quite a lot	3 (12.0)
Not at all/ little[a]	0 (0)	Very much	4 (16.0)
Quite a lot	4 (16)	A great deal	18 (72.0)
Very much	10 (40)	Description of counsellor (prompted)	
A great deal	11 (44)	Knowledgeable	24 (96.0)
Changes in knowledge, behaviour and health/emotional status as a result of the intervention (n=24)		Kind	24 (96.0)
I drink less alcohol now	13 (54.2)	Directive	23 (92.0)
I smoke less cigarettes now	12 (50.0)	Judgemental	1 (4.0)
I use drugs less now	0 (0.0)	Helpful	24 (96.0)
I quit smoking cigarettes	8 (32.0)	Non-judgemental	20 (80.0)
I know more about tobacco's negative effects	16 (66.7)	Easy-going	23 (92.0)
I know more about alcohol's negative effects	16 (66.7)	Gentle	18 (72.0)
I learned a skill I can use	12 (50.0)	Trustworthy	24 (96.0)
I am more adherent to my TB medication	23 (95.8)	Good listener	23 (92.0)
I am more adherent to my ARTs	12 (50.0)	Warm	24 (96.0)
I feel in a better emotional health	21 (87.5)	Cold	0 (0.0)
I feel in a better physical health	19 (79.2)	Scolding	0 (0.0)
I started ART treatment as a result of the intervention	8 (33.3)	Other (loving, caring and polite)	3 (12.0)

[a]Answers to two categories were grouped together. These categories are separated by /.

Table 3: TB patients' experience and satisfaction with the SMS-programme (N=25)

Variable	n (%)
Perceived helpfulness of this aspect of the intervention	
Very helpful/ Somewhat helpful*	10 (40.0)
Helpful	6 (24.0)
Somewhat unhelpful/Very unhelpful*	9 (36.0)
Perceived length	
Far too long/A bit too long*	4 (16.0)
The right length	17 (68.0)
A bit too short/Far too short*	4 (16.0)
Perceived frequency	
Far too frequently/A bit too frequently*	3 (12.0)
Frequently enough	17 (68.0)
A bit too infrequently/Far too infrequently*	5 (20.0)
Messages were easy to understand	8 (32.0)
Perceived length of period of receiving the messages	
Should have lasted much longer/Should have lasted a bit longer*	23 (92.0)
Just right	0 (0.0)
Should have been stopped a bit earlier/ much earlier*	2 (8.0)
Perceived discomfort if other people had seen the messages	
Extremely comfortable/ Very comfortable/Comfortable*	22 (88.0)
A bit uncomfortable/Very uncomfortable*	3 (12.0)
Understanding of the languages used in the messages	
Very easy to understand/Somewhat easy to understand	10 (40.0)
Easy to understand	13 (52.0)
Somewhat difficult to understand/ Very difficult to understand	2 (8.0)

*Answers to two categories were grouped together. These categories are separated by /.