Systematic Development of Structured Semi-interactive Stroke Prevention Package for Secondary Stroke Prevention

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Abstract

Background: Lack of compliance to medication and uncontrolled risk factors are associated with increased risk of recurrent stroke and acute coronary syndrome in patients with recent stroke. Multimodal patient education may be a strategy to improve the compliance to medication and early adoption of nonpharmacological measures to reduce the vascular risk factor burden in patients with stroke. We thus aim to develop multilingual short messaging services (SMS), print, and audio-visual secondary stroke prevention patient education package. The efficacy of the package will be tested in a randomized control trial to prevent major cardiovascular and cerebrovascular events. **Methods:** In the *formative* stage, intervention materials (SMS, video, and workbook) were developed. In the *acceptability* stage, the package was independently assessed and modified by the stakeholders involved in the stroke patient care and local language experts. The modified stroke prevention package was tested for implementation issues (*implementation* stage). **Results:** Sixty-nine SMS, six videos, and workbook with 11 chapters with 15 activities were developed in English language with a mean ± SD SMOG index of 9.1 ± 0.4. A total of 355 stakeholders including patients (24.8%), caregivers (24.8%), doctors (10.4%), nurses (14.1%), local language experts (2.8%), physiotherapists (13.2%), and research coordinators (9.8%) participated in 10 acceptability stage meetings. The mean Patient Education Material Assessment Tool understandability score in all languages for SMS, video scripts, and workbook was 95.2 ± 2.6%, 95.2 ± 4.4%, and 95.3 ± 3.6%, respectively. The patients [$n = 20$, mean age of 70.3 ± 10.6 years and median interquartile range (IQR) baseline NIHSS 1 (0–3)] or the research coordinators ($n = 2$) noted no implementation issues at the end of 1 month. **Conclusion:** An implementable complex multilingual patient education material could be developed in a stepwise manner. The efficacy of the package to prevent major adverse cardiovascular events is being tested in the SPRINT INDIA study.

Keywords: Acceptability, education, formative research, prevention, recurrent stroke, self-management

INTRODUCTION

In patients with first ever stroke, there is high risk of recurrent stroke and myocardial infarction and this risk persists even at 5 years after stroke.[1,2] Educational interventions may help to modify patient's lifestyle, increase adherence to medication, and control modifiable risk factors, and may be useful to prevent recurrence of stroke.[3] Motivation and positive reinforcement are needed for a sustainable behavior change. The education material can be delivered by hospital staff at the time of discharge, stroke ward-nurse, community health workers, family friends, or in a group session. These strategies to change the structure of care pathway are resource intensive. Self-management of the stroke risk factor may be an effective strategy for secondary stroke prevention.[4] However, training for self-management for secondary prevention has to be multipronged, automated, front-loaded, practical, and sustained.

Mobile phone usage has increased over period of last two decades. According to the International Telecommunication Union statistics of 2018, the number of mobile phone subscription is more than the world population, 96% of world population is covered by the current mobile network, and 90% of world population has Internet coverage. Thus, using mobile calling and text messaging for training patients with cardiovascular and cerebrovascular diseases for self-management of risk factors could be a useful approach.[5,6]

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However, patients may receive multitude of spam text messages every day, thus burying the important messages. Training of self-management of risk factors by text messaging alone has limitations of words, technically, complex messages cannot be given, and may not be associated with decrease in major cardiovascular and cerebrovascular outcomes.[7,8]

Video-assisted patient education presented as an entertaining narrative may be an effective tool for secondary prevention even in patient with poor literacy.[9] Patient and provider stroke prevention workbook has also been shown to improve self-efficacy by providing practical health information and reinforcing healthy behavior.[10,11] A comprehensive method may be needed for effective therapeutic patient education for self-management for secondary prevention after stroke.[12]

The development of such a comprehensive tool has to undergo steps of formative research to define the context, problem, and optimize intervention.[13] In a multilingual and culturally diverse population, the intervention development will have to be tailored by stakeholders including patients, family members, nurses, doctors, and physical therapist to be acceptable.[14] It is also important to pilot test the complex intervention for sufficient duration to assess implementation issues for patients and provider.

We aim to develop multilingual short messaging services (SMS), print, and audio-visual secondary stroke prevention patient education package.

METHODS

Study design

The Secondary Prevention by Structured Semi-interactive Stroke Prevention Package in INDIA (SPRINT INDIA) Study is a multicenter, randomized, parallel-design, adaptive, and blinded end-point clinical trial of subacute stroke patients (clinicaltrials.gov Registration number: NCT03228979/ ctri.nic.in: CTRI/2017/09/009600). The patient/family in the intervention arm will receive a Structured Semi-interactive Stroke Prevention Package including workbook, SMS, and health education videos for a period of 1 year in addition to standard of care. The development of Intervention package was done in three phases: formative stage (developing preliminary package in English language), acceptability stage (refinement of the intervention package with help of stakeholders in all 11 Indian languages), and implementation stage (feasibility study at two centers to assess issues with delivery of the intervention package) [Figure 1]. Local Institutional ethics committee approved the study at each participating center. Written informed consent was obtained from all patients or caregivers participating during the implementation stage.

Formative stage

The SPRINT INDIA core team performed a systematic review with the context of secondary prevention, problem of recurrent stroke/acute coronary syndrome, and intervention of therapeutic patient education to improve self-management
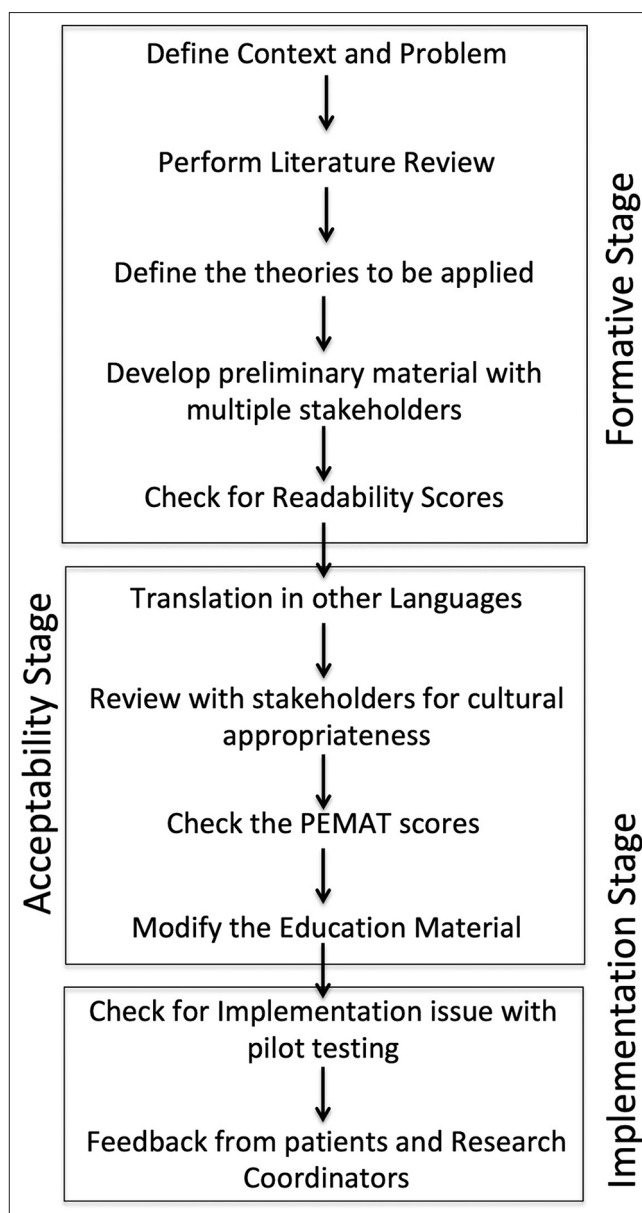

Figure 1: Algorithm for development of Multilingual patient education material for secondary stroke prevention

of stroke risk factors (hypertension, diabetes, dyslipidemia, atrial fibrillation, decreased physical activity, diet poor in green vegetables and fruits, smoking, alcohol obesity, stress/ depression, and domestic air pollution). Components identified to improve clinical outcome included medication adherence, risk factor awareness, risk factor control, adaption of healthy behavior, and sustenance of the self-efficacy efforts. To improve the adherence to the stroke prevention medication, an IMB (Information-Motivation-Behavior) model, developed by Fisher and colleagues was used. The model suggests that a person with relevant knowledge and motivation (intrinsic and extrinsic) is likely to adopt a medical adherence behavior.[15,16]

To develop material for stroke risk factor awareness and control, we used Health Belief Model (HBM). The HBM

construct takes in to account the patients' perception of susceptibility to a risk factor, severity of consequences, benefits/barriers of controlling risk factors, cues to action to change behavior, and self-efficacy or the ability to action to bring about the change on behavior.[17] To improve adaptation of healthy behavior and also sustenance of the self-efficacy efforts, social cognitive theory was used.[18] Human health is a social matter. The views of people with a similar disease are more likely to induce long-term change in behavior (a surrogate of social support) [Table 1].

SPRINT INDIA Core team of Stroke physicians and Clinical researchers developed the preliminary intervention package including SMS, videos, and a workbook in English. The SMS were aimed to have a problem and solution (positive sentiment) targeting different risk factors. Short videos (2–4 min) were made with age-appropriate commercial actors with engaging narrative presentation having a pan India appeal. The stroke prevention workbook covered what is stroke to set the context, what are risk factors to define the problem and life after stroke. To make the workbook interactive, activities were added including stroke prevention board games to be played with a dice, match the correct pairs, true and false statements, simple physical exercises, and an exercise calendar. Each chapter of the workbook was modified to get > 90 score on the Centre for Disease Control (CDC) Clear Communication Index.[19] The readability of the intervention material was assessed with SMOG (Simple Measure of Gobbledygook) index on the Readable.io website.[20]

Acceptability stage

The preliminary material developed was translated in 10 Indian languages. The translated material was sent to regional centers to conduct a half-day review meeting with the stakeholders in stroke care and local linguistic expert. The principal investigator, research coordinator, and local language expert first reviewed the content for gross mistakes and correction. The meeting included stroke patients, family members of stroke patients, doctors, nurses, physical therapist, and local language expert. The minimum quorum of the meeting was 30. During the meeting, the context of stroke was explained to the participants. They were first asked to comment and grade SMS with Patient Education Material Assessment Tool for printable material (PEMAT-P).[21] Briefly, the PEMAT tool is a systematic method to evaluate and compare the understandability and actionability of patient education materials. The education

material is understandable if the consumer from diverse backgrounds and varying levels of health literacy can process and explain the key messages. The education material is actionable if the consumer of diverse background and varying health literacy can identify what they can do based on the information presented. PEMAT tool is developed for both print and audiovisual forms of education material. All the SMS were read out in local language by the research coordinator. Second, videos were shown and participants were asked to comment and grade with PEMAT for audio-visual material. Lastly, the workbook was reviewed in detail and participants were given a copy. In addition, few games were played to see if the participants found them interesting. The participants were asked to grade the workbook with the PEMAT-P. The SPRINT INDIA core committee remotely attended the meetings. All the suggestions from the regional meeting were compiled individually, categorized, reviewed, and if feasible/relevant were adopted for each language.

Implementation stage

The modified intervention material was then pilot tested for implementation issues at two SPRINT INDIA study sites. Twenty patients were consented and randomized. The patients were followed for a period of 1 month. The ten patients in the intervention arm received the SMS daily, videos weekly, and had workbook for 1 month. The study participants in the intervention arm were assessed with a pre and postintervention questionnaires after 1 month. The control arm study participants were assessed for medication adherence. The research coordinator also completed a questionnaire to assess ease of intervention material delivery. The questionnaires were modeled on the symmetric five-grade Likert scale of agreement and disagreement.

Statistical analysis

SMOG index used to score readability is a ratio, a continuous variable. PEMAT scores are expressed as mean ± SD percentages for each study site. To assess if there was difference in PEMAT score between languages, multiple group comparison was done suing ANOVA and post-hoc analysis was done with Bonferroni correction. For the implementation phase, descriptive analysis was done for the demographic, clinical, and imaging characteristics of patients in implementation phase. Fischer Exact test (type stroke and sex) and Student t-test (age, NIHSS) are used to compare

Table 1: Theories of the intervention material development

Variable	Theory	Example
Medication adherence	Information- Motivation- Behavior Model	**SMS:** If your Blood Pressure is on target today, it may be because of the low salt intake and medications, congratulations and keep going.
Risk-factor Awareness Risk-factor Control	Health Belief Model	**Workbook:** A total of 8 chapters discuss about what is risk and self-management of individual risk factor.
Healthy Behavior Sustenance of Healthy Behavior	Social Cognitive theory (Self-efficacy and Social Support)	**Videos**: A couple is celebrating their 25th marriage anniversary on pledge for another 25 years with good control of BP and Glucose. **Workbook:** The book has eight stories of real-life stroke survivors who have gone back to work.

the intervention and control arm. The survey scores in the implementation are expressed as mean percentages in the intervention and control arms.

RESULTS

Formative stage

Stroke prevention SMS

A total of 69 messages were created in six categories (Stroke in general-6, risk factors-38, medication adherence-6, physical activity-6, nutrition-7, and rehabilitation-6). The readability SMOG index and average grade level for the SMS are 8.7 and 6.8, respectively. The tone is overall neutral and sentiment is positive.

Stroke prevention video

A total 6 stroke prevention video of mean 3 ± 0.8 min duration were produced in 6 categories including increasing physical activity, knowing atrial fibrillation, categories of medication, what is stroke, improving medication adherence, and control of BP/glucose. The readability SMOG index of video scripts is mean 8.9 ± 0.8 and mean average grade level is 6.6 ± 0.9. The tone is conversational in 4, formal in 1 and neutral in 1. The sentiment was positive in all the videos.

Stroke prevention workbook

The workbook has a total of 11 chapters (covering stroke, risk factors and life after stroke), eight short stories of stroke survivors from all over India, and 15 activities/dice games to be played with family and friends. The content of the workbook was divided in six parts to be completed in 6 weeks. All chapters had a key message in the beginning. The mean $\pm$ SD SMOG index of the workbook chapters was 9.6 ± 1.2. The mean average grade level was 8 ± 1.2. The tone was neutral in 90.1% (10/11) and sentiment was positive in 90.1% (10/11).

Acceptability stage

The preliminary material was translated in 10 Indian languages (Assamese, Bangla, Gujarati, Hindi, Kannada, Malayalam, Marathi, Punjabi, Tamil, and Telugu). A total of 355 stakeholders including patients 24.8%(88), caregivers 24.8% (88), doctors 10.4% (37), nurses 14.1% (50), local language experts 2.8% (10), physiotherapists 13.2% (47), and research coordinators 9.8% (35) participated in 10 meetings at the regional centers. The mean PEMAT understandability score in all languages for SMS, video scripts, and workbook was $95.2 \pm 2.6\%$, $95.2 \pm 4.4\%$, and $95.3 \pm 3.6\%$, respectively. The mean PEMAT action-ability score in all languages for SMS, video scripts, and workbook was $98.9 \pm 1.6\%$, $98.9 \pm 1.0\%$, and $94.2 \pm 9.2\%$, respectively. The understandability scores for SMS were lower in Punjabi language, for videos in Gujarati and Telugu, and for workbook Gujarati, Punjabi, and Telugu compared to other languages on post-hoc analysis [Table 2]. The action-ability scores were lower in Telugu and Gujarati languages compared to other languages on post-hoc analysis [Table 2].

A total of 46 suggestions were received after the meetings 12 for SMS (grammatical errors, add target numbers, digits in

local language, avoid double negative, avoid medical terms, and shorter sentences), 7 for video (add video for young stroke category, correct grammatical errors, and dubbing could have been better), and 27 for workbook (keep more picture of exercise categories and food items, chapter of lipids, risk factors, and atrial fibrillation is very technical to change, mention only major side-effects of medications, shorten the sentences further, and correct typing errors). The SPRINT core team and regional language center reviewed the education material individually. All suggestions were then included except addition of new video for young stroke separately as the purpose of education material was to be as generalizable as possible.

Implementation stage

A total of 20 patients were included in the implementation stage with mean age of 70.3 ± 10.6 years, 15% were females and median (IQR) NIHSS 1 (0–3) at the baseline. Eleven patients were randomized to the intervention arm and nine to the control arm. The baseline characteristics were comparable in the groups, except the symptom onset to randomization duration greater in intervention group [Table 3]. On follow-up at 1 month, the research coordinator found it easy or very easy to conduct the visits. The patients in the intervention group received all the 30 SMS, 4 videos, and 1 workbook. In the control arm, two patients did not have plans to visit the doctors, whereas all patients in intervention arm had plans to visit the doctor at 1 month. No adverse cerebrovascular or cardiovascular events were recorded during the study period.

DISCUSSION

In our study, we demonstrated that complex multilingual patient education material can be developed in a stepwise approach. The SMS, video, and workbook developed had a good readability score. After translation to multiple languages, the interventional material was acceptable. On the pilot testing the intervention delivery, no implementation issues were noted.

The average grade level of the SMS video scripts and workbook in our study was 6 to 8th. The workbook had CDC clear communication index >90. These findings are in line with the recommendation of U.S Department of Health and Human Services Plain Writing Act. Reading ability and associated health literacy are important for good outcomes if the target is self-management.[22] However, most of the patient education material on Internet is not compliant with current guidelines.[23,24] Further, we used IMB, HBM, and Social Cognitive theory to develop our material to improve self-efficacy. A recent study SMS4 Stroke used HBM and Social Cognitive theory for developing text messages to improve adherence of medication in patients with stroke. A total of 200 patients received SMS as a reminder for medication and twice-weekly health information for 2 months. There was 2.6 mmHg decrease in diastolic BP and improvement in medication adherence.[25]

Table 2: The PEMAT scores of the SMS, video, and workbook in different languages

Languages	SMS Mean±SD (%)		Videos Mean±SD (%)		Workbook Mean±SD (%)	
	Understandability Score	Action ability Score	Understandability Score	Action ability Score	Understandability Score	Action ability Score
Assamese	98.0±6.82	98.5±8.57	98.2±5.44	100	97.1±5.38	98.0±5.45
Bangla	97.7±5.78	100	98.8±3.50	100	99.3±2.87	99.1±3.82
Gujarati	93.4±11.0	100	91.7±10.67*	97.0±9.74	89.2±11.08*	90.9±11.86*
Hindi	96.6±7.79	96.3±17.50	98.8±3.65	100	97.0±7.33	98.2±6.70
Kannada	96.1±7.17	100	94.6±7.83	97.7±8.47	96.4±6.50	96.7±8.08
Malayalam	97.4±7.46	100	99.2±3.07	99.0±5.89	97.5±8.53	98.4±4.94
Marathi	97.4±6.60	100	99.0±2.83	99.1±5.41	98.1±6.65	98.7±4.56
Punjabi	87.7±15.5*	95.6±14.40	94.49±10.29	97.1±12.6	89.3±14.49*	93.6±16.43
Tamil	95.0±8.91	98.3±9.13	99.2±3.17	98.9±6.09	98.1±2.91	100
Telugu	92.2±8.46	100	87.5±17.98*	100	89.8±14.72*	67.7±6.09*
P	<0.001	0.240	<0.001	0.244	<0.001	<0.001

Table 3: Characteristics of patients in the implementation phase

Variables	Intervention Arm	Control Arm	*P*
Age, mean±SD years	71.4±10.2	69.1±10.9	0.6
Sex (male: female)	9:2	8:1	1
NIHSS, median (IQR)	1 (0-1.5)	2 (1-3.5)	0.2
Symptom onset to randomization, median (IQR) days	54.5 (44-89)	20 (5.5-32)	0.03
Type of stroke (ischemic stroke: intracerebral hemorrhage)	9:2	7:2	1
Hypertension, *n* (%)	7 (63.6)	6 (66.7)	1
Basal metabolic index, (kg/m²)	26±4.4	24±3.3	0.3
Antiplatelet medication at 1 month	9	7	1
Plan to meet a doctor	11	7	0.2
Ease of conducting the screening visit	11	9	1
Ease of conducting the first visit	10	9	1

The intervention study in our study material was acceptable in multiple languages with high understand-ability and action-ability scores on PEMAT. Scores in few languages were lower. The qualitative inputs obtained from those study sites were used to improve the content for the implementation stage. DREAM-GLOBAL described the development of SMS for hypertension control in Canadian aboriginal (English) and Tanzanian (Swahili) rural population.[14] Four focus group interviews were conducted with 45 participants. They noted six key areas which can create discrepancies in patients understanding: negative or nonaffirming framing of advocacies, fear-inducing content, authoritarian content, incongruity with cultural practices, disconnect with diversity of cultures within a population, and lack of clarity/practicality of the content. In most of our intervention material, the sentiment was positive and tone was neutral or conversational to address factors hindering effective translation. According to the census of 2011, translation in 10 languages allowed us to cover 86% native language speakers of Indian population, thus increasing the likelihood of generalizability of the efficacy study results.

During the pilot testing in our study, we did not note any implementation challenges to deliver, receive, or use the study intervention material. There is increased use of mobile phone for health education to improvise self-management of chronic disease. A recent feasibility study to assess smartphone-enabled educational intervention for physical disabilities after stroke did not observe any operational issues at home. More than 90% of participants felt it to be relevant and useful.[26] Self-management may improve the control of lifestyle-associated risk factors.[4,10]

Our study provides a template to develop multilingual patient education material. Use of multiple languages allowed us to be inclusive. The process is sequential. It is important to involve all the stakeholders in the care of patients. We also involved a language expert to understand the diversity in language in the same region. We used standard objective tools to score the study intervention material. A minimum of 30 stakeholders attended the acceptability stage meetings. The content material was modified according to the inputs provided by the stakeholders in the acceptability stage meetings. The pilot implementation stage was not associated with any challenges. The limitation of our study is that we could not assess readability scores of the translated material as no uniform scoring system is available for all the 10 languages. However, that lacuna may have been circumvented by the use of PEMAT scores.

CONCLUSION

Complex multilingual patient education material needs a stepwise approach for development with involvement of stakeholders. It should be objectively assessed at all stages. The study material should be developed with the purpose to alter behavior. The secondary stroke prevention package will be evaluated for efficacy in the ongoing SPRINT INDIA study.

Declaration of patient consent

The authors certify that they have obtained all appropriate participant consent forms. In the form, the participants have given their consent for their images and other clinical

information to be reported in the journal. The participants understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Conflicts of interest

There are no conflicts of interest.

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