

Development, validation and evaluation of a novel self-instructional module in patients with chronic non-specific low back pain

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ABSTRACT

Background: Low back pain (LBP) is ranked highest in terms of disability-adjusted life-years lived. Patient education and self-management have shown to play a crucial role in the overall pain management. However, the literature on the same with respect to Indian context is still lacking. The study was aimed to develop, validate and assess the acceptability and effectiveness of self-instructional educational module among Indian chronic LBP (CLBP) patients.

Methods: A prospective single-arm open-label study was conducted in a pain clinic of a tertiary care public hospital in North India with 'Backcare booklet-self-instructional module (SIM)' as an intervention in patients with CLBP. SIM was developed with the intent to provide up-to-date evidence-based information in an easy understanding way to patients with CLBP. 132 patients were administered SIM with a single session of verbal explanation. Pain intensity (numeric rating scale [NRS]), disability, fear-avoidance belief Questionnaire (FABQ), quality of life (EQ5D) and knowledge level were assessed at baseline and after 3 months of intervention. Student's paired *t*-test and Chi-square test were used. Data were analysed using SPSS version 15.0.

Results: 120 patients successfully completed the 3 months' follow-up. Significant reductions were observed in pain intensity (76[12] vs 55 [15, $P < 0.01$]; disability (51[14] vs 43 [10], $P < 0.01$); FABQ (46[12] vs 41 [10], $P < 0.01$); EQ5D (0.35 [0.27] vs 0.18 [0.26], $P < 0.01$).

Conclusion: Backcare booklet as an intervention, along with usual pharmacological care is a cost-effective educational medium to promote self-management of CLBP in the clinical outpatient settings.

Key words: Low back pain, EQ5D, fear-avoidance belief questionnaire (FABQ), functional disability, knowledge level, pain intensity, self-instruction module

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INTRODUCTION

Globally, low back pain (LBP) causes more disability than any other condition.^[1] According to the study on Global Burden of Disease 2016, LBP is ranked among the top five causes of years lived with disability (YLDs) amongst 328 studied conditions.^[2] In India, back and neck pain is ranked second leading cause of YLDs after iron-deficiency anaemia.^[2] Chronic LBP (CLBP) is often progressive with multifactorial aetiology and poses a huge economic, social and medical burden. At the societal level, LBP causes extensive financial loss

due to healthcare expenditure, work absenteeism and disability insurance.^[3]

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Patient education and self-management play a crucial role in the overall pain amelioration and development of coping skills which could greatly enhance the efficacy outcomes and thus contribute to decrement in health care expenditures. Recent National Institute for Health and Care Excellence (NICE) guideline has put patient education and self-management as one of the key recommendations in CLBP management.^[1] Patients must be provided with information and advice customised to their needs and capabilities at all steps of the treatment pathway.^[1] With regards to non-specific LBP, the aim of patient education is to improve understanding the nature of the problem and empower them to hasten the actions to get back to normal activities followed by minimising the dependency on healthcare providers.^[4]

Different modes of education are employed (verbal, written and/or audiovisual) in clinical practice. Usually, it is provided as part of the multidisciplinary management program along with other interventions which are administered at a group or individual level.^[5] However, there is no consensus regarding the most effective mode and educational booklets are the most commonly used material for providing written information. Guideline-based back care booklet is probably the most common way of being utilised.^[5,6] Evidence suggests a noticeable improvement in CLBP with the use of educational booklet.^[6]

However, most of the studies on educational back care booklet are from the Western developed world. In contrast to medical advances in many fields, dissemination of knowledge to patients about the aetiopathogenesis and ways to prevent and manage CLBP remains sluggish in developing countries. Our literature review did not find any educational material or program to combat CLBP in India. Hence, we planned to develop an evidence-based 'Backcare booklet-self-instructional module (SIM)' for CLBP patients. The aim of the present study was to develop, validate and assess the acceptability and effectiveness of SIM among Indian CLBP patients.

METHODS

Study design and setting

This 3-month prospective, single-arm, open-label, non-randomised trial was conducted in pain clinic of a tertiary care public hospital in north India with 'Backcare booklet-SIM' as an intervention in patients with CLBP after obtaining written informed consent.

Institute ethics committee approved the study. The study was prospectively registered with the Clinical Trial Registry of India (CTRI/2014/09/00547). This was an investigator-initiated study and intramural institutional resources and funding were primarily utilised.

Patient selection

Adult patients (18–65 years) of either gender with diagnosed CLBP, with or without radiating leg pain, for ≥ 3 months, having numeric rating scale (0–100 NRS) score of at least 40 in the past month at screening visit were eligible for recruitment. The diagnosis of CLBP was ascertained on the presenting symptoms and signs as well as investigations like MRI or CT scan. It was also essential for patients to be fluent in English in order to read and understand SIM. Patients must be able to comply with the planned follow-up schedule.

The exclusion criteria were patients with chronic pain of other aetiologies, presence of intellectual disability or with a history of illness that itself can cause depression independently and spinal surgery in the past. Patients were asked about the major events in the past like death or any losses, substance abuse or any conflicts to rule out the other causes of depression. The patients participating in any other study were also excluded.

Study intervention: Backcare booklet-self-instructional module

Development

SIM was developed with the intent to provide up-to-date evidence-based information in an easy understanding way to patients with LBP. The stages involved in the development were: i) literature search; ii) creation of pictures of postures and exercises; iii) preparation of SIM with evidence-based information and pictorial representation and iv) consultation of stakeholders in pain management including physiotherapists, orthopaedicians, neurologists, neurosurgeons, rheumatologists, general physicians, gynaecologists, etc., We reviewed published booklets/leaflets/brochures on LBP, clinical practice guidelines and organised relevant information into various parts, which included basics of back, postures and ergonomics, exercises, do's & don'ts and facts and myths. SIM was developed in simple English language.

Validation

Developed SIM was circulated among stakeholders of pain management (orthopaedicians, rheumatologists,

general physicians, neurologists, neurosurgeons, physiotherapists, pain physicians and medical experts) and the targeted audience for the content validity and face validity assessment; and modified according to their opinions. For validation of the booklet two instruments, proposed by Castro *et al.* for the development and validation of a method for the evaluation of printed education material, were employed.^[7] The instrument for the content validity and face validity was filled by the experts ($n = 10$) and the target audience (CLBP-positive patients) ($n = 10$), respectively. A total of 52 items were distributed comprising seven evaluative domains; two related to content validity (scientific accuracy and content) and the remaining five regarding face validity (literary presentation, illustrations, sufficiently specific and understandable material, legibility and printing characteristics and quality information). The response for the items related to content validity was collected on 4-point Likert scale based on the expert's answers classified as (1) not relevant, (2) need some revision, (3) relevant but need minor revision and (4) very relevant and for the face validity classified as (1) totally disagree, (2) partially agree, (3) agree and (4) totally agree. The content validity index (CVI) was calculated for the quantification of the feedback received from the experts.

Finally, a 40-pages SIM containing information about basics/biomechanics of the spine, LBP (explaining definition, types, various pain generators, etc.) and its risk factors, symptoms, warning signs, management, misconceptions, facts and myths, coloured images of postural advice and exercises was developed and validated.

Study procedure

All patients attending pain clinic during the phase of data collection were screened for eligibility criteria. Eligible patients willing to participate in the study were enrolled. Informed consent was obtained. All patients received usual care as per the institutional protocol in addition to SIM during the study.

At enrolment, demographic and disease assessment was performed using a pre-designed case record form by a trained interviewer as well as pain physician.

Following baseline assessment, patients and accompanying caregiver (if any) were explained about SIM. Each individual session lasted for around 30 min. Patients were advised to read SIM back at home and

encouraged to follow the instructions and guidance provided in it.

Effectiveness measures

In this feasibility study, to estimate the impact of SIM on patients' beliefs and early clinical change, the outcome variables were assessed at baseline and 3-month face-to-face follow-up visit.

1. Pain intensity

Pain intensity was measured using 100 points (0 as no pain and 100 representing the worst imaginable pain) NRS.^[8]

2. Functional disability

Functional disability was assessed using Modified Oswestry Low Back Pain Disability Questionnaire (MODQ)^[9] which covers 10 domains of functional ability, that is, pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, travelling and employment/homemaking with a score ranging from 0 to 50 (higher scores represent severe disability). The total score (ranging from 0 to 50) is multiplied by two and expressed as a percentage for MODQ index (MODQI)

3. Fear-avoidance belief questionnaire (FABQ)

The FABQ (0–96) is a questionnaire consisting of 16 items with each item scored on a point scale of 0 to 6. High values suggest increased levels of fear-avoidance beliefs.^[10] Two validated sub-scales, that is, a work subscale consisting of seven items (FABQ-W; range: 0–42 points) and a physical activity subscale consisting of four items (FABQ-PA; range: 0–24 points) were also used as measurement tools for the study.^[11]

4. Quality of life (EQ-5D)

EuroQol-5D (EQ-5D) is a standardised measure of health status across five dimensions viz. mobility, pain/discomfort, usual activities, self-care and anxiety/depression with the hierarchy of responses consisting of five levels (no problem, slight problem, moderate problem, severe problem and extreme problem). The health state using EQ-5D was defined using a unique 5-digit numeric code developed by combining the level of response from each of the five dimensions. This code was further valued for a single index score which ranges from -0.109 to 1.0 . The calculation of the EQ-5D index score was based on the value set for the United Kingdom, as no value set for India is available.^[12] The permission for the same was

sought from the EuroQol group. The visual analogue scale (EQ-5D VAS) which is a part of EQ-5D was not used in the study.

5. Knowledge level

Knowledge level was assessed by employing a questionnaire consisting of 10-items with a score range of 0–10. Higher scores represent higher knowledge level. The questionnaire was developed based on the information of SIM and modified after face validity assessment from experts (orthopaedicians, rheumatologists, general physicians, neurologists, pain physicians and medical experts). After which it was tested on 10 patients, so as to ensure that it accurately measures what it aims to do, irrespective of the responder. Thereafter, the developed questionnaire was used for collecting data.

Statistical analysis

The analysis was per protocol (analysis was performed for those participants who completed the follow-up at 3 months). A pre and post-test analysis was done where continuous values were expressed as mean with standard deviation (SD) and numbers as percentages. The outcome efficacy was compared using student's paired *t*-test between time points for continuous variable and Chi-square test was used for categorical variables. *P* value ≤ 0.05 was considered statistically significant. Data were analysed using SPSS version 15.0.

RESULTS

190 patients with CLBP were screened of whom 146 (77%) patients met the inclusion criteria. 14 (7%) patients were not willing to participate. Hence, 132 (70%) patients were finally recruited and were administered SIM with verbal explanation session of 30 min in addition to usual care. Of 132 patients, 12 (9%) respondents were lost to follow-up and, thus, 120 (91%) patients successfully completed the follow-up as shown in Figure 1.

Baseline characteristics

Out of 120 patients, 64 (53%) were males. The mean (SD) age and duration of pain were 45 (15) years and 42 (48) months, respectively. At baseline, average pain was severe as assessed using NRS 76 (12) along with severe functional disability [MODQ scores, 51 (14)]. A high fear-avoidance belief was observed with both FABQ-PA 17 (5) and FABQ-W 29 (8) with an overall FABQ score of 46 (12) as shown in Table 1.

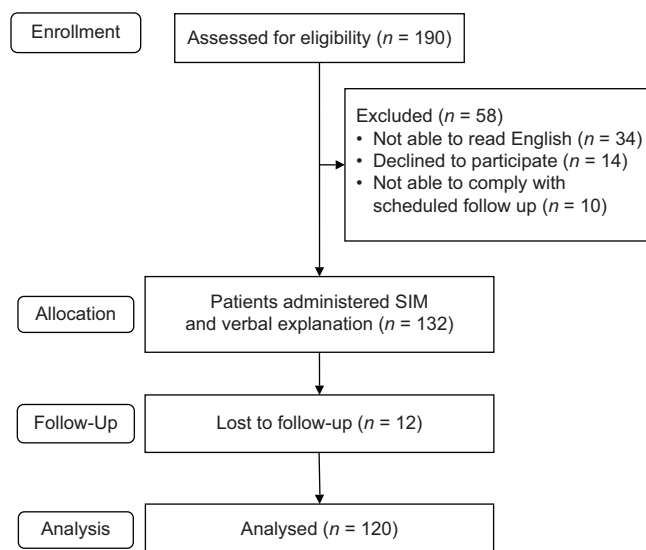


Figure 1: Flow diagram of patients

Table 1: Baseline characteristics of patients with CLBP (n=120)

Parameter	Mean (SD)
Age (year)	45 (15)
Male, n (%)	64 (53)
BMI*	27 (4)
Smoking, n (%)	25 (20)
Alcohol, n (%)	18 (15)
Duration of low back pain (months)	42 (48)
Pain* (on 0-100)	76 (12)
Disability# (0-100%)	51 (14)
FABQ-PA	17 (5)
FABQ-W	29 (8)
FABQ	46 (12)
EQ5D	0.35 (0.27)
Knowledge level	4.3 (1.3)

Data presented as mean and standard deviation unless otherwise specified. n: Frequency; BMI: Body mass index; FABQ-PA: Fear-avoidance beliefs about physical activity; FABQ-W: Fear-avoidance beliefs about work. *Pain was assessed using numeric rating scale. #Disability was assessed using modified Oswestry disability Index

91% of patients had taken analgesics, 56% NSAIDs, 19% muscle relaxants and 12% had received epidural steroids in the past.

Content validity

The draft of a booklet for scientific accuracy and content was evaluated by a team of 10 experts. The team consisted of six (60%) males and the minimum professional degree of post-graduation was attained by the experts. The age of the experts ranged from 31 to 58 years, mean (SD) of 44.1 (9.9) years. The CVI for the 'scientific accuracy' and the 'content' was obtained as 0.85 and 0.82 respectively, indicating an excellent level of agreement among the experts for this aspect. The overall CVI of the booklet was 0.84 and was considered validated for content.

Face validity

A total of 10 LBP positive patients (50% males) were enrolled to determine the face validity of the SIM. The age range from 29 to 57 years, with mean (SD) of 41.8 (8.7) years and all the patients had at least a middle school certificate. The level of agreement amongst the target audience was high ranging from 93.6% to 99.1%. The face validity index obtained for various domains is as following: literary presentation (93.6%); illustrations (98.3%); sufficiently specific and comprehensive material (99.1%); legibility and printing characteristics (97.5%); quality of information (98.3%).

Compliance

All participants (100%) reported reading at least part of the book; 80 (66%) reportedly reading the full book, 18 (15%) read more than two-third while 22 (18%) participants reportedly read between one-third and two-thirds of the book.

Study outcomes

A significant reduction in pain intensity was observed (76[12] vs 55 [15], $P < 0.01$), though 38% patients still reported persistent pain at 3-month follow-up visit. Patients did not report any change in the intake of NSAIDS, antiepileptics or other prescribed analgesics in the past 3 months.

Significant improvement in functional ability as assessed using MODQI was observed from baseline 51 (14) to 3 months 46 (10), $P < 0.01$. Fears and beliefs were high at baseline, with overall FABQ mean scores of 46 (12) which was significantly reduced to 41 (10), $P < 0.01$. A total of 95 (79%) of patients had strong fears and beliefs about back pain at baseline.

Similarly, there was significant improvement in health-related quality of life (EQ-5D) at follow-up visit (0.35 [0.27] vs 0.18 [0.26], $P < 0.01$). We observed improvement in all five dimensions of EQ5D viz. mobility, pain/discomfort, usual activities, self-care and anxiety/depression.

Knowledge scores showed a significant increase as a result of the health education intervention administered in the form of SIM and advice (4.3 [1.3] vs 6.4[1.4], $P < 0.01$). Table 2 shows changes from baseline to post-intervention on pain severity, disability, fear-avoidance beliefs, QOL and knowledge scores.

Table 2: Pre- to post-intervention changes in each of the outcome measures (n=120)

Variable	Pre-intervention Mean (SD)	Post-intervention Mean (SD)	P
Pain intensity*	76 (12)	55 (15)	<0.01
Disability [#]	51 (14)	43 (10)	<0.01
FABQ-PA	17 (5)	15 (5)	<0.01
FABQ-W	29 (8)	26 (7)	<0.01
FABQ	46 (12)	41 (10)	<0.01
EQ5D	0.35 (0.27)	0.18 (0.26)	<0.01
Knowledge level	4.3 (1.3)	6.4 (1.4)	<0.01

FABQ-PA: Fear-avoidance beliefs about physical activity; FABQ-W: Fear-avoidance beliefs about work; SD: Standard deviation. *Pain was assessed using VNRS. [#]Disability was assessed using modified Oswestry disability Index

DISCUSSION

This feasibility study largely comprises development, validation and evaluation of novel SIM in a sample of 120 CLBP patients in India. Patients reported severe pain intensity, marked functional disability and poor knowledge regarding various aspects related to LBP at baseline. Our findings of significant reduction ($P < 0.01$) in pain intensity, functional disability and fear-avoidance behaviours and improvement in QOL and knowledge level at 3 months follow-up support meticulous administration of novel SIM, with elaborated single-session instruction. The positive effect of a single-session intervention to significantly reduce pain-related outcomes established in another study capacitates an expansion of access to the low-cost efficient mode of care in reducing pain.^[13] The single-session intervention holds much more importance in a developing country like India where the majority of the patient population visiting public hospitals come from rural and distant areas which make multiple session interventions cost-ineffective and possibly confront higher dropout rate.

The significant improvement in various pain-related outcomes in the present study as a result of using a back care booklet is in accordance with a systematic review by Henrotin *et al.*, which concluded that providing simple patient information increases understanding about LBP amongst patient and decreases pain, disability and fear.^[14] The pictorial representation of exercises and postures is an evidenced long-term solution for orthopaedic morbidities as it strengthens the muscles, joints, ligaments and tendons make them more flexible as well as resistant to injury. Studies suggest patient education, as an intervention, can be effective in the management of CLBP.^[15-19] The central focus of patient education is providing information by

a healthcare provider, which is extremely important as it can enhance self-care; use of active coping skills and can prevent unnecessary use of healthcare.^[19,20] The positive results were strongly related to the personal contact between the patient and the information provider.^[19,20] In our study, the information regarding this booklet was provided by a trained healthcare provider who also distributed this booklet to patients to take home.

Our study showed a significant reduction of pain on NRS after administering back care booklet. The band-aid approach to mask pain with drugs over time can have devastating effects on internal organs. This further strengthens the priority of administering back care booklet for rational care of CLBP patients. Only a few trials have compared a self-care booklet to other treatments.^[21-24] Cherkin *et al.* reported that massage but not acupuncture was superior to the other interventions like self-care book and videotape advice for short term in patients with back pain of ≥ 6 weeks.^[23]

Low health literacy strongly affects patients as it often contributes towards increased hospitalisation rates, poor health outcomes especially in chronic conditions and increased morbidity rates.^[25,26] Education also improves the patients' understanding of the morbid condition and enhances adherence towards an ongoing treatment. This was also reported in our study wherein, all patients at a follow-up visit reported having read the information provided in the booklet and claimed it to be understandable, useful and easy to follow. The patients also reported improved knowledge score and reduction in their fear and avoidance behaviour probably due to amelioration of their myths. Self-care skills may be particularly important in cases of CLBP which often require meticulous adherence to treatment protocols along with self-care management.

Our study reported significant improvement in the QOL and functional ability of the patients after reading back care booklet. This improvement might be associated with the reduction in back pain which eased the performing activities of daily living. Moreover, the inclination to have healthy body mechanisms may also contribute towards reducing disability.

This booklet is an evidence-based tool and its contents are in accordance with many guidelines and published literature on LBP.^[1,27,28] These guidelines signify providing information about LBP, patient education

and self-management as key recommendations in the management of LBP.^[1] This booklet emphasises on many important aspects such as getting back to normal activities, including a return to work as soon as possible as elaborated by Rantonen *et al.*^[29]. Moreover, one of the common myths prevalent amongst most patients is that they resort to bed rest as a measure of relief from pain. On the contrary, bed rest increases the probability of transforming intermittent pain to chronic persistent pain. However, maintaining an active lifestyle is the key for early recovery from CLBP, which is very well elaborated in many guidelines.^[1,27,28] Our SIM reiterated and imparted all the above information.

As the booklet is relatively inexpensive, easy to deliver and innocuous; it can be widely used and can be feasible as a part of treatment and facilitate self-care among LBP patients.^[14,30,31] Thus, educating patients with CLBP can happen at primary care clinics as it takes less effort, no need for highly skilled (however well trained) human resource and is cost-effective. The limitation of the study is not having the comparator groups, further, the effect of the analgesics acting as the confounders couldn't be ascertained. However, constant education and self-reading of educational material can help to improve CLBP and related symptoms.

CONCLUSION

The use of back care booklet as an intervention, along with usual care, resulted in a reduction of pain, disability and improvement in QOL and knowledge scores. Thus, SIM is suggested to be an effective educational measure to promote self-management of CLBP and associated symptoms.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients 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.

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Conflicts of interest

There are no conflicts of interest.

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