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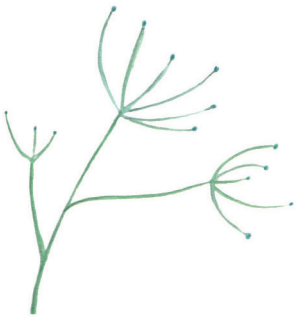
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Chapter 10

General Discussion



GENERAL DISCUSSION

Low back pain (LBP) is among the most prevalent and costly disorders and the leading cause of disability worldwide.^[1] It is important to develop interventions that aim to reduce the burden of LBP. In 2010 in the Netherlands, a multidisciplinary guideline for LBP was developed to improve care for people with LBP.^[2] To support uptake of guideline recommendations in clinical practice, active implementation of the guideline is needed. This thesis evaluated the effectiveness and cost-effectiveness of a multifaceted strategy to implement the Dutch guideline for LBP in primary care, specifically in reducing the number of referrals to secondary care and diagnostic imaging for these patients.

The following objectives were addressed in this thesis:

1. To develop a multifaceted strategy to implement the Dutch guideline in primary care including:
 - A multidisciplinary educational training for healthcare professionals;
 - An informative website for patients with LBP to increase their knowledge, and improve back beliefs and self-management.
2. To evaluate the effectiveness and cost-effectiveness of implementation of the Dutch multidisciplinary guideline for LBP through a multifaceted strategy compared with usual implementation on back beliefs, functional status, quality of life and absenteeism of patients with LBP.
3. To evaluate the effectiveness and cost-effectiveness of implementation of the multidisciplinary guideline for LBP through a multifaceted strategy compared with usual implementation on adherence of general practitioners to the guideline.
4. To evaluate the barriers and facilitators of successful implementation of the multidisciplinary guideline for LBP through a multifaceted strategy from the perspective of general practitioners, physiotherapists, occupational physicians, and patients with LBP.

To reach these objectives, a longitudinal stepped-wedge cluster randomized trial was carried out and evaluated, along with qualitative and quantitative process evaluations to study barriers and facilitators for implementation, a systematic review to study the effectiveness of multifaceted implementation strategies for LBP, and an evaluation of a Canadian mass media campaign to improve beliefs about LBP among the general public.

The current chapter will provide a summary using 6 themes: 1) Main findings, 2) Implementation, 3) Self-management, 4) Population, 5) Methodological considerations, and 6) Recommendations for research and practice.

Main findings

The stepped-wedge cluster randomized trial was not able to demonstrate that a multifaceted implementation strategy was more effective than usual care in improving back beliefs,

functional status, absenteeism or quality of life of patients with LBP (Chapter 9). It might be worthwhile to consider the strategy from a cost-effectiveness perspective (Chapter 9). The strategy costs were low (€ 70,- per patient), and the societal costs per patient were lower in the group that received the strategy than in the control group (adjusted ΔC € 748,-), mainly due to lower indirect costs (i.e. absenteeism, presenteeism, and unpaid productivity losses). Although the uncertainty surrounding the cost estimate was large, the strategy had a maximum probability of 0.88 of being cost-effective on a willingness-to-pay threshold of € 10.000 per QALY gained, increasing to a probability of 1.00 on a willingness-to-pay threshold of € 80.000 per QALY gained. Given that the strategy resulted in cost savings of € 748 per patient, a crude budget impact calculation suggests that this strategy could yield cost savings from a societal perspective of € 449 million (€ 748,- x 600.000 new patients with LBP annually).^[3]

Regarding adherence of general practitioners to the guideline, the implementation strategy did not show large effects (Chapter 8). Rates of referral and of recorded inquiries regarding psychosocial and occupational risk factors remained low in both groups over time. The only statistically significant difference found was a reduction in the number of referrals to neurologists in the implementation group (from 100 (7% of 683 patients) to 50 (4% of 671 patients)) compared to the usual care group (from 48 (4% of 580 patients) to 50 (4% of 615 patients), ($p < 0.05$)). However, the usual care group already had low referral rates at baseline. There were no other between-group differences in referrals to medical specialists or diagnostic imaging. A process evaluation among participating professionals (generals practitioners as well as occupational physicians and physiotherapists) showed that professionals were positive about the professional targeted implementation strategy, but still experience many barriers to guideline adherence (Chapter 6). These barriers include personal and practical factors (e.g. lack of time or solutions to practical barriers), confidentiality and privacy of patients, dependence and distrust issues among the HCPs, as well as policy factors (e.g. reimbursement systems do not allow for 'thinking outside the box').

A process evaluation among patients alongside the trial (Chapter 7) showed that exposure to the patient targeted strategy, i.e. the informative website, was low. One third of the patients had not used the website at all, and 43% had only used it once. Patients were positive about the website components, and satisfaction with the website increased significantly with an increase in its use. Still many reasons for not using the website were mentioned. Patients did not use the website because the information was already known to them, or their health-care provider had not recommended usage of the website (95%) or had not discussed the content of the website with them (98%).

The results of the multifaceted implementation strategy on patient and professional outcomes is comparable to nine other studies that evaluated multifaceted strategies for the

implementation of guidelines for back and neck pain in health care (Chapter 4). These studies did not show effects on patient or professional outcomes. Unfortunately, it was not clear whether the lack of effectiveness of those studies was due to theory or implementation failure, as most did not report any process evaluation measures. Instead of multifaceted implementation strategies targeted at specific patients with LBP and their healthcare providers, population-based mass media approaches can be effective in improving back beliefs of the general public. Chapter 2 and 3 evaluate a Canadian mass media campaign aimed to improve back beliefs of the general public. The mass media campaign had continued impact on public back beliefs over the course of 7 years. Improvements over time were associated with exposure to campaign messaging, and individuals with higher annual income appeared more likely to have better back beliefs.

Implementation

To implement the Dutch multidisciplinary guideline for LBP as part of the multifaceted implementation strategy, a professional targeted educational strategy was developed for general practitioners (GPs), occupational physicians (OPs), and physiotherapists (PTs). The strategy consisted of a one-off multidisciplinary continuing medical education (CME) training session, supported by take-home materials and an interactive (mobile) website. This strategy was supported by an informative website for patients with LBP. The aim of the implementation was to improve practitioner's guideline adherence, patients' back beliefs, knowledge, and self-management. To reach this goal, multidisciplinary communication and collaboration are important recommendations made by the guideline, and the training session particularly focused on this.^[2] The guideline further recommends self-management for patients, and the patient targeted strategy aimed to provide patients with the information and tools to do so. The strategy did not lead to improvements in outcomes on patient or professional level. The lack of results in the present study are similar to other studies.

Changing any type of behaviour is difficult. Implementation interventions to change clinician behaviour usually show only small to modest effects on professional behaviour.^[4-5] Many factors have been proposed to account for the difficulty in changing clinician behaviour, including the matter of habits. Healthcare professionals' daily behaviour in practice is predominantly habitual and difficult to change.^[6] A new clinical guideline can take up to 3 years to be fully implemented.^[7] It takes firm approaches to 'de-implement' old habits and implement new and more desirable behaviour. Mere distribution of guidelines and materials is therefore not enough, and active implementation is necessary. Many strategies for active implementation have been proposed, but it is still unknown what approaches work best in which setting.^[8] Identified implementation strategies to change clinical practice include interventions targeted at healthcare organisations, at healthcare workers, and at specific types of practice, conditions or settings.^[9] More specifically, implementation strategies can be divided into educational

interventions, feedback and reminders, patient-based strategies, organisational and financial measures, and combined interventions.^[8] Many studies have evaluated the effectiveness of these implementation strategies on changing physician behaviour, and the results are inconclusive. For example, educational meetings, which are commonly used for CME to improve professional practice and patient outcomes, show mostly small effects.^[10] The effectiveness of educational strategies might increase when combined with other interventions and when focusing on outcomes that are perceived as serious but do not require complex behaviours.^[10] Similarly, printed educational materials have only small beneficial effects on professional practice and patient outcomes.^[11] Another review did not find evidence that the use of eHealth interventions alone improves clinical practice or patient outcomes, but did not identify reasons for the reluctance of professionals to applying eHealth interventions.^[12] Given that many interventions seem ineffective on their own, a combination of multifaceted interventions that target various barriers to change simultaneously, are often recommended.^[8]

More specifically targeted at musculoskeletal disorders including LBP, a review showed that education for GPs and distribution of guidelines lead to no or only small improvements in GPs' clinical behaviour, and may only have a slight effect on reduction of imaging requests by GPs. Adding reminders to imaging reports resulted in a small but sustained reduction of imaging requests.^[13] As a part of this thesis, a systematic review on the effectiveness of multifaceted strategies for the implementation of guidelines for back and neck pain in primary care showed that multifaceted implementation strategies do not significantly improve professional behaviour, patient outcomes, or cost of care.^[14] An important side note made in this review is the fact that most implementation studies did not report any process measures.

Process measures of implementation strategies can be very useful and informative for various reasons. To investigate why certain implementation strategies are effective and others not, it is necessary to take a look into the 'black box' of the strategies.^[8] Process evaluations can play an important role herein as they can aid in describing the implementation strategy in detail, in evaluating the extent to which the strategy was executed as intended, and they can shed a light on the experiences of participants. With the help of process evaluations, an effort can be made to distinguish theory failure from implementation failure. Theory failure occurs when the implementation process was executed exactly as planned and no effects were found. Implementation failure occurs when the implementation process was not executed as planned. A process evaluation was performed alongside the implementation study in this thesis. This evaluation showed that the strategy was implemented as intended to a large extent, and that the strategy was positively evaluated by the professionals. However, the lack of effectiveness of the strategy might result from various barriers the professionals experienced for their adherence to the guideline recommendation. This was especially true in the case of multidisciplinary collaboration and communication. Professionals are reimbursed

by insurers for their patient contacts, not for multidisciplinary (telephone) communication initiatives that may reduce health services utilization of patients. The reimbursement system does not stimulate multidisciplinary collaboration in its' current form. Healthcare insurers and policymakers should take these considerations into account when deciding on reimbursement schemes for healthcare. Another barrier experienced by the professionals in this trial is the difficulty to share patient information and treatment advice with other professionals. This can be difficult due to practical reasons such as not being able to easily reach a colleague or due to privacy issues. These are barriers expressed by the professionals that participated in the present study, and that very well might have played a role in the lack of effectiveness of the multifaceted implementation strategy.

Self-management

Health is more than the absence of disease, it is *"the ability to adapt and to self-manage"*.^[15] Self-management, the act of patients' learning and using strategies to manage and monitor their own health, is consistently recommended in international guidelines for the management of LBP.^[16] Despite its' growing popularity, many questions regarding self-management are left unanswered. Self-management interventions may vary on several components: how they are delivered (e.g. individual or group interventions; electronic or print interventions), by whom they are delivered (e.g. by the healthcare provider or the 'lay internet'), and what they deliver (e.g. educational information or physical activity).^[17] A systematic review that aimed to identify effective delivery styles and content for self-management interventions for chronic musculoskeletal pain sought an answer to these questions.^[17] This review showed that self-management interventions were promising on patient outcomes if they were delivered in a group setting, healthcare practitioners were involved, lasted less than 8 weeks, and had a psychological component to them.^[17] In another review, Oliveira and colleagues investigated the effectiveness of self-management specifically for LBP.^[18] They found that self-management showed only modest effects for pain and disability compared to minimal interventions, and inconsistent effects when compared to other interventions. They also found that audio-visual resources providing information on self-management, and group discussions delivered via websites had only trivial effects when compared to minimal interventions. However, the content and modes of delivery of their included studies varied widely and the evidence they found was only of moderate quality.^[18] Important questions thus remain unanswered: what works for whom, in which way, and when?

One possible mode of delivery that has gained increased attention over the past few years is eHealth (often also referred to as telemedicine, telehealth, mobile or mHealth).^[19] eHealth refers to the delivery of health care through modern technology, with or without interference from professional healthcare providers, and has been proposed as a promising mode of delivery for self-management programs.^[20] Digital self-management interventions have shown

promise for improving chronic pain, including LBP, compared to usual care or no interventions.^[21] Web-based interventions also showed useful when offering a psychological component or having an interactive approach, and showed particular promise for improving catastrophizing and attitudes in patients with LBP.^[22] Given that eHealth is still in its' infancy, these findings need to be interpreted with caution. Several challenges for effective application of eHealth remain. One of these challenges lies in the healthcare practice. Healthcare providers need to be ready and able to integrate eHealth into their daily practice, but they have insufficient knowledge, incentive, and infrastructure to do so.^[20, 23-24] The upcoming of eHealth requires healthcare providers to adapt to a new way of providing health services and a new role in their relationship with patients. Although patients are increasingly well-informed and able to make shared decisions regarding their treatment, healthcare providers still have an important, although changing, role in this. Research has shown that patients are more keen on using eHealth if the service is actively promoted by their healthcare provider, as (s)he is considered the most highly trusted health information source.^[25-26]

The patient targeted strategy presented in this thesis combined the promise of both self-management and eHealth in order to improve patient beliefs about LBP, disability, quality of life, and absenteeism. An informative (mobile) website containing written information, exercises and, most importantly video messages aimed to improve self-management of patients with LBP. The website was provided to patients during 12 months, and was mainly focused on continuing activities of daily living, promoting physical activity, and encouraging (return to) work. This strategy did not lead to improved patient outcomes.

The characteristics of this strategy are at odds with the characteristics of the promising interventions in the systematic review by Carnes and colleagues as discussed above.^[17] Those interventions were, for example of shorter duration (<8 weeks). This makes sense when considering that most patients with LBP have a good prognosis, recovering markedly within six weeks after onset.^[27] Interventions of longer duration might only be of interest to people with chronic LBP, while it is always important to consider what information is provided to patients at what time point. In the current study, participants indicated that much of the information provided in the website was already known to them, which may be because of their high educational level. If the information was known to them, the website provided was redundant, resulting in a lack of effectiveness in the present study.

Although the healthcare providers involved in the study were expected to promote and discuss the website with their patients with LBP, this was only done in 5% (promoting the website) and 2% (discussing the website). The process evaluation showed that these participants too considered the website more trustworthy and worthwhile if their healthcare provider was actively involved. Given the evidence regarding the importance of healthcare

provider involvement in eHealth (i.e. blended eHealth), there is a lot to be gained from increasing healthcare providers' attention for eHealth. This is a task not only for researchers, but for policymakers as well.

Population

About 60% of the participating patients in this study were female, and participants predominantly had attained a high educational level, had predominantly work that was not physically demanding, and were more than 150 minutes physically active per week (WHO guideline).^[28] Ninety-three percent were of Dutch nationality, the average scores on the Back Beliefs Questionnaire were relatively negative (25). They had low disability levels (average 5 points on Roland Morris Disability Questionnaire (RMDQ)), and high quality of life scores. Furthermore, 40% of the participants did not have LBP anymore at the start of the study. These characteristics might have been of influence on the observed results of this study, raising the question if the strategy would be effective in a different population, e.g. patients with more pronounced LBP, lower educational levels and quality of life, and higher disability levels and absenteeism rates.

Other studies that investigated LBP in primary care showed different patient characteristics than the present study. For example, merged data from primary care prospective cohort studies in the United Kingdom included data from 2526 participants.^[29] In that cohort, the gender distribution of participants (58% female) was similar to that of the present study, but the distribution of participants in 'higher social class' and 'lower social class' was fairly equal within the cohort (52 and 48% respectively). The cohort participants had higher levels of disability measured by the RMDQ (8.8) than the participants in the present study. Similar characteristics were found in another, more recent cohort study. In that cohort with 609 participants, 63% were female, had an average RMDQ score of 12.7, and only 22% had a high socio-economic level.^[30] What stands out here, is that in populations with lower educational and/or socio-economic status, the levels of disability are higher. Indeed, it has been shown that there is an inverse relationship between socio-economic status and the occurrence of LBP, with low levels of education being associated with increased prevalence of LBP, delayed recovery, prolonged episode duration, and poor outcomes.^[31-32] A Canadian LBP mass media campaign evaluated in this thesis (Chapter 3) also showed that higher annual household income, a proxy measure for socio-economic status, is significantly associated with more positive back beliefs, i.e. people with a higher income agreeing more often with the statement "If you have back pain you should try to stay active" than people with a lower income. Socio-economic status usually refers to the social standing or class of an individual, and other fields of study have repeatedly shown it is strongly associated with health disparities.^[33-34] It is interesting to investigate the relationship between socio-economic status and LBP, and the role socio-economic status plays in LBP interventions.

Although it is known that the prevalence of LBP and care seeking patterns for LBP are similar between ethnicities, in the present study as much as 93% of participants were native Dutch.^[35-36] Of the participants in an Australian study on the characteristics of patients with LBP in primary care, only 30% were not native Australian (born outside Australia).^[37] A survey from the general population in Alberta, Canada (presented in this thesis in Chapter 3) also showed that 93% of almost 10.000 participants were native English or French speakers; although this may not necessarily mean they were native Canadians, but could have been immigrants from English or French speaking countries. It raises the question whether non-native (minority) patients are underrepresented in scientific research regarding LBP, which touches on the issues of equality and disparities in health, care, and research. Although minorities are as willing as non-minorities to participate in health research, it is known that racial and ethnic minorities, and individuals of low socio-economic status are underrepresented among participants in clinical trials.^[38-40] Several studies have investigated barriers and facilitators to participation of minorities in health research. One important barrier is the cultural and linguistic appropriateness of recruitment strategies and interventions.^[41-42] It has been shown that response rates to recruitment increase by 8% when the recruitment letter is personalized compared to general information and population based sampling strategies, and culturally adapted intervention programs increase the completion of these programs by minority participants.^[42] In the present study, minority participation was supported by the translation of the recruitment letter and parts of the website. However, these initiatives did not result in increased recruitment or retention of minority participants in the present study (Chapter 7). Therefore, it is necessary to look further than cultural and linguistic adaptations. For example, community involvement prior to the start of a study, e.g. by matching recruitment and study staff to the targeted population may reach a more successful recruitment rate of minorities.^[41-42] Another important barrier is the issue of trust. Mistrust has frequently been associated with the perception that the research will only benefit natives or the research institute instead of the minorities within the community.^[41] Mistrust can be addressed by involving community organisations or stakeholders, and trusted individuals such as the personal healthcare provider, as has also been shown in the present study (Chapter 9).^[41]

Given that healthcare costs for LBP are generally high due to disability and productivity losses at work and the fact that this was not true for the participants of the present study further raises the question of generalizability of the results of the present study. It suggests that the strategy evaluated should be examined in a more appropriate population, keeping in mind the various demographic characteristics of and barriers perceived by the target population. A different setting than the one of the present study (i.e. GPs in an academic network) might provide patients with different characteristics.

Methodological considerations

There are several methodological features of this thesis to be considered.

The first thing to consider is the recruitment and retention of participants. Patient recruitment took place each quarter and retrospectively. Patients who had visited their general practitioner in the previous quarter were invited to participate in this study by traditional mailing. The invitations were prepared by the research staff, but the general practitioners were responsible for the actual invitations. This led to a delay in recruitment, because practitioners took up to 4 weeks to select and invite their patients. For some patients this meant that they had visited their practitioner up to 4 months before they were invited to participate. For other patients it also might be that the information provided through the website was already known to them and not interesting enough to keep returning to. For many patients this strategy may not have been necessary as they may have sought help elsewhere in the meantime, and this might explain the lack of effectiveness and the low participation rates. Future studies should ideally find more efficient and time-sensitive recruitment methods in order to tackle this barrier. For example, digital mailing might reduce time delays, and digital reminders integrated in the operating system of practitioners, might allow for real-time invitations of patients at the moment they might need the strategy the most: during or directly after the consultation with their practitioner, when there is still room for improvement in outcomes.

Secondly, there are some remarks regarding the professional targeted implementation strategy to improve guideline adherence. This strategy included, among other facets, a multidisciplinary training session for general practitioners, physiotherapists, and occupational physicians. The results of the current study showed that this strategy was not sufficient to reach changes in clinical practice. Although the implementation strategy seems an effective manner to create awareness of a problem and of the existing LBP guideline, more training is needed to change actual practice. As professionals perceive many barriers to collaborate with other professionals, continuous or regular training activities may provide opportunity to acquaint professionals with each other and with eHealth and increase their support of eHealth programs. However, it is not possible to be certain about the lack of effectiveness of the implementation strategy based on the present study only, since guideline adherence was measured by performance indicators that were developed for the purpose of the study and were not validated in a larger population. It is worthwhile developing and investigating appropriate instruments for measuring guideline adherence.

Another feature to consider are the outcome measures. As the current study aimed to reach improvements in outcomes through self-management, it is unclear if the chosen outcome measures were the most appropriate ones. The back beliefs of the patients were lower (i.e.

more negative) than in other studies and populations, while they had better disability and absenteeism rates. This raises the question if back beliefs are the best predictor of LBP-related health and functional outcomes.

Recommendations for research and practice

Several recommendations for research and practice can be derived from this thesis.

Recommendations for research:

1. Researchers should develop and implement effective strategies to improve implementation of clinical guidelines. It is important to investigate and address needs and barriers prior to tailoring the development of a strategy in order to prevent implementation failure.
2. Future research should take into account the setting and population in which studies are conducted. High risk patients and practices should be targeted. High risk patients include patients with low socio-economic status and quality of life, and high disability, absenteeism and presenteeism rates. High risk practices have high referral rates, which indicates room for improvement.
3. To improve use of web-based informative strategies by patients, research should perform needs assessments among patients to explore their perspectives and expectations, and adapt interventions accordingly, e.g. in terms of language, content, and delivery mode.

Recommendations for policy and practice:

1. Healthcare professionals should play an important role in the use of web-based information by patients, as patients perceive this information more trustworthy when recommended by their healthcare provider. It is important that professionals actively discuss possible trustworthy and evidence-based information provided on the internet and activate their patients to use this information.
2. Healthcare professionals and policymakers should pay attention to demographic characteristics of patients. Patients with low socio-economic status should receive extra attention, as they are more at risk for worse outcomes. Information provided to patients should be adapted to their background and needs.
3. Policymakers and healthcare insurers should be aware of barriers for guideline adherence by healthcare professionals, and ideally should adapt their policies and financing schemes accordingly in order to facilitate guideline adherence (i.e. provide and finance new ways of multidisciplinary collaboration that allows for safe and privacy-sensitive exchange of relevant patient information).

CONCLUSION

This thesis showed that a multifaceted implementation strategy did not result in improved back beliefs, disability, quality of life, or absenteeism in patients with LBP. This thesis also showed that the multifaceted professional based implementation strategy did not lead to improved guideline adherence of GPs, multidisciplinary collaboration or decreased referral rates to secondary care and diagnostic imaging for LBP. Compliance was low among participants, and blending the patient targeted strategy with the professional targeted strategy failed. Therefore, the multifaceted implementation strategy evaluated in this thesis is not recommended for widespread use in its current form.

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