Theory of Planned Behaviour Based Interventions for Health Behaviour Change in Chronic Diseases Among Low Health-literacy Population: Protocol for a Systematic Review

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Protocol

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Abstract

Background Health behaviour can change outcomes in both healthy and diseased populations and are particularly useful in promoting compliance to treatment and maintain fidelity to care seeking and follow-up options in chronic diseases. Interventions to change health behaviour based on psychological theory more often successful than those without any underlying theory. The theory of planned behaviour (TPB) is one such psychological theory which had been found to predict human behaviour with respect to disease prevention and when applied to interventions can change the outcomes of diseases. Most of the research evidence of TPB based interventions have been from developed world. Evidence is required whether TPB based interventions can be applied and works in low resource, low health literacy settings of low and middle income countries (LMICs).

Methods The protocol has been developed as per PRISMA-P guidelines and incorporates PICO (**p**opulation, **i**ntervention, **c**omparison, **o**utcomes) framework for describing the methodology. Population above 18 years of age and having any chronic disease will be selected while any health or educational intervention based on constructs of TPB will be included. Comparison will be with non TPB based interventions or treatment as usual without any intervention and the primary outcome will be the behaviour change effected by the TPB based intervention. Intervention studies will be considered and relevant databases like MEDLINE, EMBASE, Cochrane Library and ProQuest will be explored. Data extraction will done in a standardised form and quality assessment will be done using the Cochrane Collaboration's Tool for Assessing the Risk of Bias. Narrative synthesis of the selected studies will be done to draw the conclusions and meta-analysis will be done if the heterogeneity is less than 50% by I-2 statistics.

Discussion This systematic review will provide new evidence on fidelity and effectiveness of the TPB based interventions among chronic disease patients in low health literacy population of LMIC settings. This will provide us with new knowledge of how to plan and use such interventions to change health behaviour in chronic disease patients.

Systematic review registration this protocol has been registered in PROSPERO with registration no. CRD42018104890.

Background

Health behaviour refers to any behaviour that impacts on people's physical and mental health and quality of life. [1]. It is defined by Gochman, 1997 as " personal attributes such as beliefs, expectations, motives, values, perceptions, and other cognitive elements; personality characteristics, including affective and emotional states and traits; and overt behaviour patterns, actions, and habits that relate to health maintenance, to health restoration, and to health improvement" [2]. Health behaviour influences health outcomes in both healthy and unhealthy populations; whereas in healthy population they are primarily important in prevention of diseases and promotion of health, in population with diseases they can

influence quality of life. Three types of behaviour are related to population health: behaviours which 1) contribute to the prevention of disease, behaviours 2) involve care-seeking and adherence to treatment, and 3) relate to the delivery of healthcare [1]. Behaviours which involve care seeking and adherence to treatment have key influences on the health of population with chronic diseases.

Interventions targeting health behaviours are thus important and contribute to change in health outcomes. Using theory to develop health behaviour interventions has been advocated by some [3] as it provides a useful framework for identifying the key modifiable determinants of health behaviour, designing interventions to target these determinants and accumulating evidence. A number of systematic reviews have reported that using theory in shaping interventions leads to greater effectiveness in changing health behaviour than interventions developed without theory [4, 5].

The Theory of planned behaviour (TPB) focuses on theoretical constructs concerned with individual motivational factors as determinants of the likelihood of performing a specific behaviour. TPB assumes that the best predictor of human behaviour is behavioural intention which in turn is determined by attitude towards the behaviour, social normative perceptions regarding it and perceived control over performance of the behaviour. Interventions based on TPB have been found to be effective in changing health behaviours [6]. TPB has been found to predict if an individual engages in a wide variety of different health behaviours including exercise, undergoing a health check-up, and being screened for breast and colorectal cancers [7, 8]. TPB based interventions have improved outcomes in diseases like obesity and schizophrenia and health behaviours like fruit and vegetable intake and exercise patterns [9, 10].

Health literacy, is defined as “the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions” [11]. The concept of health literacy represents a constellation of skills necessary to function effectively in the health care environment and act appropriately on health care information; these skills include print literacy, numeracy and oral literacy [12, 13]. According to the US Department of Education survey done in 2003, approximately 80 million adults in the United States have limited health literacy, including related prose, document, and quantitative skills. Certain groups have an even higher prevalence of the problem. Such groups include the elderly, minorities, individuals who have not completed high school, adults who spoke a language other than English before starting school, and people living in poverty [14]. Highlighting the health impact of low health literacy, a 2004 systematic evidence review [15] and its update in 2011 [16] found a relationship between low health literacy and poor health outcomes. Health literacy in low or middle income countries (LMIC) is lower than that measured in the United States and other high-income countries (HIC), because by definition, general income and education of people in LMIC will be lower as a whole as well [17, 18, 19].

Therefore it is important to look into studies which have applied TPB based health interventions in chronic diseases to change health behaviours, particularly in LMIC settings (with presumably lower

health-literacy) in the context of the ever-increasing global burden of chronic diseases and how these can be applied across different communities and settings.

Methods

Aim

The aim of this review is to evaluate the effect of TPB-based interventions on changing health behaviour among population with chronic diseases in low health-literacy settings. This study also aims at finding out which types of interventions were used, the time-frame of such interventions, the modes of delivery and the settings in which these interventions were delivered. This protocol has been developed in accordance with the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) guidance [20]and draws on the Cochrane Handbook for Systematic Reviews of Interventions guidelines for developing a protocol [21].

Study types

The following study types will be considered for inclusion: interventional studies with a control arm including randomised controlled trials, quasi-experimental studies, community-based cluster randomised trials and controlled before and after studies. Case-control studies, cohort studies, reviews, case reports, case series and animal studies will be excluded.

Participants

Participants will be adults over 18 years of age with any chronic disease [22]. Healthy population and pregnant women will be excluded.

Intervention

Any educational or health intervention used on individuals or groups that documented the use of the constructs of TPB i.e. attitude towards the behaviour, subjective norms and perceived behavioural control for changing health behaviour. From a scoping search of literature, the following terms for identifying TPB will be used – behavioural beliefs, normative beliefs, control beliefs, motivation to comply and perceived power and behavioural intention, besides attitude towards the behaviour, subjective norms and perceived behavioural control.

Control groups

The control groups will have either 1) any health or educational intervention not based on any psychological theory, 2) health education based on psychological theory other than TPB or 3) treatment as usual without any education. The same group may also be used as control before the TPB-based intervention was delivered to the group and the outcomes evaluated.

Outcomes

The primary outcome will be change in health behaviour which will include preventive behaviours, adherence to treatment and care seeking. Adherence has been defined by World Health Organisation (WHO) as “the extent to which a person’s behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider”[23].

Secondary outcomes will include the constructs of TPB which were important influences to health behaviour change and moderators of these effects, including type of intervention, the time-frame of such interventions, the types of health literacy settings, the mode of delivery, the type of providers and satisfaction among patients to the intervention.

Exclusion criteria

Animal studies, studies on health behaviour change which do not mention TPB or other psychological theories and studies undertaken on healthy individuals with a purely health promotion focus will be excluded.

Study identification

The following databases will be searched for relevant studies: MEDLINE, EMBASE, COCHRANE library, Psych INFO, Web of Science, Scopus, CINAHL, ProQuest databases (ProQuest Sociology and ProQuest Social Sciences), Global Index Medicus, Bibliography of Asian Studies and IndMed. We will also search the grey literature through Open Grey and The Grey Literature Report. Search strategies will be developed for all the databases.

Study selection

The databases will be searched for relevant studies and all such records will be exported to the Endnote Library for screening, de-duplication and overall management of the records. All the studies will be screened by two independent reviewers and any disagreement will be resolved by discussion, and if necessary will be resolved by arbitration by a third reviewer. A similar process will be followed for full screening of full-text studies. Multiple publications of the same study utilising the same data set will be taken as one study. In case of missing data efforts will be made to contact the authors to request the data. If the full text article for a particular study title or abstract is not freely available through our library resources, external request through an inter-library loan will be made; if this isn’t successful the authors will be approached to provide the full text article. Studies arriving after the cut-off date will be not included but their titles will be mentioned along with the reasons for non-inclusion.

Data extraction and management

A data extraction form will be developed and standardised; it will be piloted and revised before the start of the review. The data extraction form will be adapted from the Cochrane Collaboration data collection form of randomised controlled trials (RCTs) and non-RCTs intervention review [24]. Data extraction will be performed by two independent reviewers and any discrepancies will be resolved by discussion; if still disagreement persists it will be arbitrated by a third reviewer.

Quality Assessment

Quality and risk of bias for all potential studies will be evaluated using the Cochrane Collaboration's Tool for Assessing the Risk of Bias, RoB 2 [24]. As per the guidelines in the Cochrane Handbook of Systematic Reviews of Interventions, the studies will be assessed as per standard criteria and will be labelled as 'low', 'unclear' or 'high' risk of bias.

Analysis

All the characteristics of included studies will be presented in a tabular form with the description of study design, type of disease, type of intervention used, no. of groups involved, outcomes and methods of assessment and risk of bias in each study. The fidelity of the studies will also be assessed, i.e. the number of people completing the intervention and reasons for non-compliance. We will do a narrative synthesis of the studies to draw the conclusions. Whether or not we will do a pooled quantitative estimation (meta-analysis) will depend on the type and heterogeneity of the studies. We will follow the guidance provided in the handbook of Cochrane systematic review to evaluate the heterogeneity. As we expect a high level of heterogeneity, we will apply random effect model. Perhaps, when I-2 statistics is more than 50% we will not do meta- analysis. We intended to explore the reason for heterogeneity with the following subgroup analysis – low-health literacy, types of intervention and modes of delivery.

We intend to do a sensitivity analysis by excluding high risk of bias studies to evaluate the robustness of the overall pooled estimate.

Grading of overall strength of evidence

We will attempt to apply the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach [24] for creating a summary of findings table. The GRADEpro Guideline Development Tool (GDT), an online tool will be used for either importing the data from Revman or manually adding numerical data into the software for each outcome. The GRADE approach has five domains; risk of bias, inconsistency, indirectness, imprecision and publication bias to evaluate the certainty of evidence for randomised studies. The four levels of evidence of GRADE will be applied, i.e. very low, low, moderate and high.

Registration and reporting

The study is registered with the University of York Centre for Reviews and Dissemination International prospective register of systematic reviews (PROSPERO) with registration no. CRD42018104890. The review will be reported in accordance with the PRISMA guidelines for reporting of systematic reviews. Any amendments to the protocol made during the process of the systematic review will be reported in the final report with rationale for such modifications.

The review team

The search for databases and retrieval of studies, screening, data extraction and quality assessment will be performed independently by BP and RK. BP will work under the guidance of MD. RK is an experienced reviewer working with Cochrane Collaboration – South Asia and well experienced in conducting systematic reviews. MD, DW or RI will arbitrate any disagreements in the review process and will provide field expertise in synthesising the data. DW and RI are experienced researchers; DW and DM have a substantial experience in undertaking systematic reviews.

Discussion

It is known that TPB is effective in changing behaviours and there is evidence on ways the different constructs of TPB explain these changes. However, there is little specific information on the change in health behaviour brought about by TPB-based interventions in chronic diseases and their applicability in different settings – in particular, LMICs. This review will add to the evidence base of understanding and applying the TPB-based interventions in changing health behaviour in chronic diseases in low health literacy settings which will inform prevention and treatment approaches.

Existing reviews in this field

Three other similar reviews have been undertaken. Wendy Hardeman et al [25] examined interventions based on TPB to change health behaviour; however, it focussed on behaviour change on any population where TPB has been applied without any mention of chronic diseases. This review, conducted in 2001, also indicated that TPB was mainly used to measure process and outcome variables and to predict intention and behaviour, and less commonly to develop the intervention.

A second, more recent review, by Steinmetz et al [10] incorporated a three level meta-analysis to establish that interventions based on TPB were effective in changing behaviour; there was a mean effect size of .50 and effect sizes ranging from .14 to .68 for changes in antecedent variables (behavioural, normative, and control beliefs, attitude, subjective norm, perceived behavioural control, and intention). This review examined behaviour change across all behavioural domains and types of conditions were not specified.

Thirdly, Antonia Rich et al [26] examined, in 2015, the role of TPB in predicting adherence in people with a chronic condition. The review suggested that TPB makes a useful contribution to our understanding of adherence in chronic illness; it measured the types of adherence behaviours, adherence measures and the effects of the TPB constructs on adherence behaviour. However, it didn’t specify interventions were based solely on TPB but considered any type of study referencing TPB and using any of the constructs of TPB. Further, it didn’t examine the settings in which the interventions were delivered or had any reference to health-literacy and excluded studies with populations considered to be at risk of chronic disease (e.g. sedentary adults).

The present review looks to evaluate the role of TPB based interventions in patients with chronic diseases and the health behaviour change that may occur in such cases, particularly in low-health literacy

populations of low-and-middle income countries (LMICs). It also seeks to describe the type of change, the settings and moderators for such change and the types of interventions effecting such change.

Conclusion

The burden of death and disability due to chronic diseases is increasing. Many of these patients suffer lifelong from these conditions and changing health behaviour can improve the quality of life of such individuals by applying theory of planned behaviour-based health interventions. Evidence is needed about the applicability of TPB-based interventions for behaviour change in chronic diseases in low health literacy settings - and we need to understand the different moderators influencing such change. This review will help in gathering evidence in these under-reviewed areas, and help researchers and policy makers to plan such intervention programmes for both prevention and treatment.

List Of Abbreviations

GDT Guideline Development Tool

GRADE Grading of Recommendations Assessment, Development and Evaluation

HIC High income country

LMIC Low- and middle-income country

PRISMA-P Preferred Reporting Items for Systematic review and Meta-Analysis Protocols

PROSPERO International Prospective Register of Systematic Reviews

RCT Randomised Control Trial

TPB Theory of Planned Behaviour

WHO World Health Organisation

Declarations

- Ethics approval and consent to participate – Ethical approval for this study was granted by the local ethics committee of Christian Medical College, Vellore, India known as the Institutional Review Board (IRB) of CMC Vellore vide IRB min no. 11381 dated 27.06.2018. and approval was granted from the Health Ministry's Screening Committee of Indian Council of Medical Research with proposal id 2018-0706. This study is one part of a large mixed-method study which was approved by the IRB of Christian Medical College and the Research Governance body of the University of Edinburgh.
- Consent for publication – Not applicable.

- Availability of data and materials – Data sharing is not applicable to this article as no datasets were generated or analysed during the current study
- Competing interests – The authors declare that they have no competing interests
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- Authors' contributions – BP, DW and LG conceived the idea for this work. It was drafted by BP, supported by RP and MD, which was then revised after several rounds of critical comments from DW and MD, LG and RI. The RESPIRE collaboration was involved in critical review of the manuscript and all the authors approved the final version.
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