A primary care web-based intervention modelling experiment replicated behaviour changes seen in earlier paper-based experiment

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Abstract

Objectives: To evaluate the robustness of the Intervention Modelling Experiment (IME) methodology as a way of developing and testing behaviour change interventions prior to a full-scale trial by replicating an earlier paper-based IME.

Study design and setting: Three-arm, web-based randomised evaluation of two interventions (persuasive communication and action plan) and a 'no intervention' comparator. The interventions were designed to reduce the number of antibiotic prescriptions in the management of uncomplicated upper respiratory tract infection. General practitioners (GPs) were invited to complete an online questionnaire and eight clinical scenarios where an antibiotic might be considered.

Results: 129 GPs completed the questionnaire. GPs receiving the persuasive communication did not prescribe an antibiotic in 0.70 more scenarios (95% confidence interval = 0.17 to 1.24) than those in the control arm. For the action plan, GPs did not prescribe an antibiotic in 0.63 (95% CI = 0.11 to 1.15) more scenarios than those in the control arm. Unlike the earlier IME, behavioural intention was unaffected by the interventions; this may be due to a smaller sample size than intended.

Conclusions: A web-based IME largely replicated the findings of an earlier paper-based study, providing confidence in the IME methodology.

Keywords: intervention modelling experiments, behaviour change, randomised controlled trials, prescribing, primary care

Word count: 2240

What's new?

- A web-based Intervention Modelling Experiment (IME) replicated the findings of an earlier paper-based IME on general practitioners' simulated antibiotic prescribing behavior. The web-based IME did not replicate findings linked to behavioural intention.
- Intervention effects were robust across different modes of intervention delivery.
- This work supports the view that IME methodology is a robust choice for exploratory work developing and evaluating complex behaviour change interventions prior to evaluating them in a full-scale trial.
- Replication studies are relatively rare. This replication experiment demonstrated that the IME methodology can be considered as a robust way of developing theory-based behaviour change interventions.

Background

Without help, the uptake of research results into clinical practice happens slowly, if it happens at all [1]. The field of *implementation science* (or *knowledge translation* as it is generally called in North America) has been established to, among other things, develop and evaluate interventions to support professional behaviour change that translates research evidence into practice. Examples include audit and feedback [2] and educational outreach [3]. However, the literature provides less information to guide the choice, or to optimise the components, of these interventions for use in different contexts [4, 5]. Interventions can be effective (e.g. reminder systems, audit) but the evidence is conflicting and the reason for this is largely unknown [2]. The UK Medical Research Council (MRC) framework for developing and evaluating complex interventions proposes more and better theoretical and exploratory work prior to a full-scale trial as a means of improving intervention development [6].

Intervention modelling experiments (IMEs) are one way of doing this exploratory work [7]. In an IME key elements of the intervention are delivered, using a randomised design, in a manner that approximates the real world but where the measured outcome is generally an interim outcome, a proxy for the behaviour of interest. To evaluate the robustness of the IME methodology, we conducted a web-based IME study [8] that replicated an earlier paper-based IME, which evaluated two theory-based interventions to reduce antibiotic prescribing for upper respiratory tract infections (URTI) in primary care [9,10]. Replication is essential if waste in research is to be reduced; a single success is rarely sufficiently compelling to support widespread adoption [11].

A detailed description of the form and content of the two theory-based interventions has been published elsewhere [12]. This paper describes a randomised evaluation of two behaviour change interventions (a persuasive communication and an action plan) with a ‘no intervention’ comparator, all of which were delivered within a web-based IME.

Methods

The trial was a three-arm, web-based trial of two behaviour change interventions compared to no intervention. Participants were general practitioners (GPs) from 12 Scottish Health Boards identified by the Scottish Primary Care Research Network (SPCRN; www.sspc.ac.uk/) using a combination of publicly available information provided by Information Services Division (ISD) Scotland (http://www.isdscotland.org/isd/3793.html) and restricted information held on the NHS.net database, the latter to provide e-mail addresses. The decision to use email to invite GPs was taken after a randomised evaluation of postal versus email invitations, which found emails to be as effective as postal invitations but quicker and cheaper to send [13].

Recruitment

Recruitment was done in two stages, reflecting the stages of an IME [8]. The first stage recruited GPs to complete an online questionnaire comprising 20 questions about antibiotic prescribing behaviour, eight clinical scenarios that required antibiotic prescribing decisions and four general questions about the GP's background. GPs were also offered a £20 voucher. These data were used to identify predictors of antibiotic-prescribing behaviour, which replicated work from the earlier paper-based IME [9], as well as to design a new intervention [12]. The clinical content of all eight scenarios, provided by one of the authors (MPE), was such that there were no clear cases for prescribing an antibiotic.

The second stage recruited from among the GPs responding to stage 1 but excluded those in the first quartile of responses to the questionnaire's 'intention to not prescribe antibiotics' questions. GPs already following best evidence for prescribing antibiotics were not candidates for our interventions. The remaining 75% of GPs were invited to complete a second online questionnaire, which this time included one of the two interventions or the 'no intervention' comparator. The eight scenarios in the second questionnaire were different to those in the first but again, they were created (by MPE) so that there was no compelling case in any of them for prescribing an antibiotic. The other 24 questions were the same as in the first questionnaire. The full questionnaire is shown in Additional File 1.

GPs were randomly allocated to one of the interventions or the comparator by the LifeGuide software (https://www.lifeguideonline.org), which we used to deliver the web-based IME. Participants were offered a voucher for £30 and non-responders received two reminders spaced two weeks apart. All research staff, except SPCRN staff, were blinded to GP recruitment allocation until the study database was locked.

Sample size

Using the dependent variable of behavioural intention, we sought to detect an effect size of 0.66, which was the mean effect size for change in intention in a meta-analysis of trials that measured change in intention and behaviour [14]. We needed 50 participants per group to have 90% power of detecting this effect size at a significance level of 5%, or 150 participants in total. The recruitment target was set at 250 GPs to achieve the sample size of 150 participants. This increase

was to allow for drop-out between questionnaires and excluding the first quartile of responses to the 'intention not to prescribe antibiotics' questions (see above).

Interventions

Two behaviour change interventions were evaluated: a *persuasive communication* and an *action plan*. The persuasive communication addressed beliefs about the consequences (e.g. including 'attitude' from the Theory of Planned Behaviour and 'outcome expectancies' from Social Cognitive Theory) of managing patients with uncomplicated URTI without prescribing antibiotics. It was effective in reducing the number of antibiotic prescriptions in the paper-based IME's prescribing scenarios [10]. The format of this intervention can be translated entirely for web delivery, therefore repeating it in the current study would address questions about both intervention effectiveness and the relative effectiveness of paper versus web-based delivery of intervention materials. (See Additional File 2).

The action plan was a new intervention developed using data from the first online questionnaire [12]. Based on the stage 1 questionnaire responses, predictors of antibiotic-prescribing behaviour were identified and classified into 'theoretical domains' of behaviour change. Three domains predicted prescribing rates and were thus identified as targets in the new intervention. These domains were beliefs about consequences, beliefs about capabilities and behavioural regulation. Replicable behaviour change techniques (intervention components) have been identified to target each of the domains [15]. A behaviour change technique known to influence the last two of these three domains is action planning. An action plan is an explicit statement of where, when, and how a behaviour will be performed.

Action plans are proposed to work by setting up environmental cues to remind an individual to perform the behaviour [16]. Furthermore, repeated performance of a behaviour in response to the cue increases the likelihood that a behaviour may become a habit. (See Additional File 3).

Finally, a 'no intervention' comparator was used, in other words the web-based IME presented nothing to the GP and moved straight to the questionnaire and scenarios.

Outcome measures

There were two outcomes for the trial:

1. *Behavioural intention* - strength of motivation, or intention to perform the target behaviour (i.e. not prescribing an antibiotic).
2. *Behavioural simulation* - clinical decisions in the context of simulated clinical situations presented in the eight clinical scenarios.

Behavioural intention was measured using three questions from the questionnaire: Q16, Q17 and Q18. (See Additional Files 1 and 4). The intention score was computed by computing the mean of the responses (range of 1 to 7) on these three items.

Behavioural simulation was the total number of clinical scenarios out of eight where an antibiotic was not prescribed.

Statistical analysis

Categorical data were described using numbers and percentages, continuous data using mean and standard deviation. The two outcomes were analysed using linear regression comparing action plan and persuasive communication with the 'no-intervention' comparator. The models were adjusted for baseline and the effect sizes presented along with 95% confidence intervals and p-values and analysed by intention to treat. Analysis was carried out using Stata 13 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP).

Results

A total of 198 GPs were randomised (Figure 1). Of these, 129 were from the lower three quartiles of the 'intention to not prescribe antibiotics' responses in the first stage, i.e. our target group, and all 129 sets of these data were analysed.

Equivalence of groups

The demographic characteristics of the participants across the three trial arms were similar (Table 1).

Behavioural intention and behavioural simulation

The mean number of scenarios without a prescription was 5.0 (out of 8) for the persuasive communication, 4.9 for the action plan and 4.2 for the 'no intervention' comparator (Table 2). Figure 2 shows the distribution of scenarios without an antibiotic prescription for the interventions and comparator.

The results of the regression analysis for behavioural simulation are also summarised in Table 2. Adjusted for baseline score, GPs receiving the persuasive communication did not prescribe an antibiotic in 0.70 (95% confidence interval = 0.17 to 1.24) more scenarios than those in the control arm. For the action plan intervention, GPs did not prescribe an antibiotic in 0.63 (95% CI = 0.11 to 1.15) more scenarios than those in the control arm.

Behavioural intention was unaffected by both interventions (Table 2). Correlation between intention and behavioural simulation was 0.13, indicating a weak relationship between the two.

Discussion

The work described here is part of a study to evaluate the IME methodology itself by replicating an earlier, paper-based IME [9, 10]. Our key research interests were:

1. Does the delivery mode of the IME (paper or web) affect predictors of GP behaviour?
2. Do interventions developed using these predictors change behavioural intention and simulated behaviour in similar ways for the paper and web-based IMEs?

This is important information because, for the IME methodology to be useful, it needs to be a robust and reliable method to support trialists with their intervention modelling work. The first aim was addressed in an earlier publication [12], which

showed that the web-based IME identified 8/10 of the predictors of prescribing behaviour identified in the paper-based IME and therefore suggested similar interventions (e.g. persuasive communication, action planning) to those suggested by the paper-based IME. This was reassuring.

This paper describes a randomised evaluation of two interventions - a persuasive communication used in the paper-based IME and an action plan developed from the predictors described in our earlier publication [12] - against a 'no intervention' comparator. To again be reassured, we would have expected the persuasive communication intervention to reduce intention to prescribe an antibiotic and to reduce antibiotic prescribing in simulated clinical scenarios. For the persuasive communication, we would also expect the size of effect seen in the current work to be similar to that seen in the earlier, paper-based IME.

Both interventions increased the number of scenarios without an antibiotic prescription, as in the earlier study. The results seen in the current study for the persuasive communication are in broad agreement with those obtained for the same intervention in the paper-based IME (paper-based IME: increase of 0.47 (95% CI=0.19 to 0.74) scenarios without a prescription; web-based IME: increase of 0.70 (0.17 to 1.24) without a prescription. However, neither intervention reduced the intention to prescribe, although both sets of confidence intervals shown in Table 2 for behavioural intention do not rule out a reduction. However, we would not necessarily expect the action planning intervention to influence behavioural intention, as the proposed mechanism by which action plans change behaviour is similar to the mechanism involved in habit formation; that is, the behaviour is

triggered directly by the context, with minimal reasoning or ‘cognitive processing’ [17]. Hence, following action planning, behaviour could change without the involvement of behavioural intention (which is a cognitive process).

The study had three strengths: it replicates previous work, it used a randomised design and it had a theoretical rationale for selecting intervention components. The work described here, together with that in a sister paper [12], have largely reproduced results obtained in an earlier, paper-based IME [9, 10], which reassures us that the IME methodology is robust. The randomised design is the best way of running an experiment to test the effectiveness of proposed interventions.

There are two limitations. The first is inherent in the IME methodology and is that vignettes were used to provide clinical scenarios. This was discussed in our earlier publication [12] but, in summary, although strong evidence of the external validity of vignettes is limited, studies that have explored this have been favourable towards their use [18]. The second limitation is that only 129, not 150 of GPs from the first stage took part in the second stage. That we could only persuade 129 of them to respond to the second questionnaire is unfortunate and may explain our wide confidence intervals and failure to replicate the reduction in intention to prescribe as seen in Hrisos et al’s earlier work [10].

Conclusion

We have replicated, in a web-based system, an IME delivered initially on paper and we found changes in behavioural simulation that are consistent with those found in the paper-based IME. We did not replicate the changes in behavioral intention seen in the paper-based work. We have also evaluated a new behaviour change intervention in a randomised trial and found that it changed behavioural simulation as expected based on its theory-based design. Replication studies are an important part of increasing value and reducing waste in research [11] and this replication study gives us greater confidence in the IME methodology than a single study.

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Ethical approval

WIME was approved by the Tayside Committee on Medical Research Ethics A, Research Ethics Committee reference 10/S1401/54 and received NHS Research

& Development approval from the 12 National Health Service (NHS) Health Boards involved.

The trial of which this study is part is registered: ClinicalTrials.gov number NCT01206738.

Authors' contributions

All authors except JH contributed to the design of the study. KB did most of the day-to-day running of the study, with support from CJ and ST. GM and JH analysed the data and KB, GM, DB, JJF, JH and ST discussed the results. All authors contributed to the interpretation of the results. ST was chief investigator of the study and wrote the first draft of the paper. All authors contributed to the final version. All authors have approved the final manuscript.

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Table and figure legends

Table 1 Baseline characteristics.

Table 2 Behavioral simulation and behavioural intention. For behavioral simulation, the data presented are for number of scenarios where GPs did not prescribe an antibiotic. For behavioral intention, the data presented are for the sum of four questionnaire items linked to intention (see main text for details). Higher scores reflect a stronger intention to not prescribe an antibiotic.

Figure 1 Participant flow. Note: [1]This breaks down as 254 GPs from the first stage of the IME and 260 GPs who were not involved in the first stage. [2]Forty GPs were from the upper quartile group of the first stage responders and were unfortunately invited to participate in stage 2 due to an administrative error. The remaining 26 (of the 198) were GPs who were not in the first stage but who were invited because we were unsure that 150 target GPs would respond, which turned out to be correct. The analysis presented in this paper focuses on the 129 GPs from our target group and for whom we have baseline 'intention to not prescribe antibiotics' data.

Figure 2 The distribution of the number of scenarios (out of 8) for which 129 GPs did not prescribe an antibiotic for the Persuasive communication, Action plan and 'No intervention' control.