Author’s response to reviews

Title: Development of an intervention to facilitate implementation and uptake of diabetic retinopathy screening,

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Author’s response to reviews:

Reviewer #1

I appreciate the focus given to including stakeholders or end-users throughout the development process, and hope you consider telling us "how" you did this in another manuscript (for example: dealing with power relations, ensuring representativeness, building relationships of trust).

A separate Study Within a Trial was conducted to examine the conduct and experience of participants in the consensus groups. We have referenced this paper which is currently under review:

Line 259 - 262
Further details on the consensus group meetings, including recruitment of patients and members of the public are provided as part of a SWAT (Study Within A Trial) which observed group dynamics and gathered data on participants’ experiences of the meetings [76].

In the discussion section, we also refer to the challenge of navigating tensions between theory-based, systematic intervention design, and co-design with end-users, in the Implications section:

Line 572-583

Secondly, integrating the contributions of the different groups across our process was a key challenge, particularly as professional and patient preferences did not always align. Ultimately we resolved to make evidence-based decisions, incorporating a final check to ensure we addressed salient theoretical domains (barriers and facilitators), and weighing the contributions of patients and professionals according to the nature of their feedback, for example, professional feedback on issues of feasibility (e.g. reminder delivery mode), and patient feedback on issues of acceptability (reminder messages) were given more weight. Given some of the challenges outlined by the current study, future studies should consider how to structure and sequence user involvement. This could be done by incorporating final ‘checks’ of user suggestions to check whether these are in line with theory or existing evidence or seeking the input of users on theory-informed intervention elements that have been designed by researchers.

I appreciate the distinction between the clinical intervention and the implementation intervention. Please consider making this distinction explicit in the abstract.

We have added the following in the abstract:

Line 31 - 32

‘Implementation interventions’ refer to methods used to enhance the adoption and implementation of clinical interventions such as diabetic retinopathy screening (DRS).

Please clarify the timeline of development. The interviews with stakeholders / end-users took place July 2014, January 2015, April 2016, February 2017 (lines 165 - 166). You state the intervention was developed 2018/2019. Please clarify if you see the interviews as part of the intervention development, and if so would the timeframe for development be 2014 - 2019?

We have now specified that core development took place 2018/19. Data from interviews conducted from 2014-2017 were analysed as part of this process

Line 171

The core intervention development work took place in 2018/2019 when the national screening programme had begun to introduce new approaches to facilitate participation [66].

Line 187-189
To identify barriers and enablers, we analysed existing qualitative data collected as part of a study to understand patient and professional experiences of DRS, among other diabetes services. Patient interviews were conducted by MT (July 2014 and January 2015) (see Acknowledgements).

There is both mention of stages of development and steps of development. Please consider choosing either steps (in the abstract, line 154, and then in subheadings) or stages (line 154) or explaining how the steps are rolled up into the stages.

We have ensured the terminology is now consistent throughout the manuscript. Our approach is based on that outlined by French et al. As they used ‘steps’, we have modified the manuscript throughout to refer to steps or stepped approach rather than stages.

Given general practitioners are a key influential stakeholder, line 440 "largely relies on GP endorsement", could you clarify the number of GP's included in stakeholder interviews?

We have clarified this now:

Line 316 – 318

In addition to the 47 patient interviews (Suppl. Table 2), 22 interviews were conducted with (GPs (n = 5), practice nurses (n = 9), and DNS (n = 8), and 2 focus groups (4 per group) were conducted with community DNS (n = 8).

As the intervention involves endorsement by primary care professionals (i.e. both GPs and practice nurses) on reflection, we felt it was more accurate to amend this sentence as follows:

Line 487-488

The intervention is delivered through primary care and largely relies on endorsement from primary care HCPs.

Please clarify the sentence in line 155-156 which refers to using TiDieR and Proctor et al. Are these informing the development? Or does it refer to reporting the implementation intervention in this manuscript? Or both? This checklist was used for reporting:

Line 174

The final intervention was reported according to guidance from TiDieR [69] and Proctor et al. [28]

In reference to the qualitative interviews (lines 165 - 172), where were they conducted? By whom were they conducted? I see in the Acknowledgements Dr. Tracey conducted the patient interviews. It might be worth clarifying this for the reader in this section.
We have clarified these details. We have also restructured this section to order relevant information by patient interviews and HCP interviews.

Line 187 -189

To identify barriers and enablers, we analysed existing qualitative data collected as part of a study to understand patient and professional experiences of DRS among other diabetes services. Patient interviews were conducted by MT (July 2014 and January 2015) (see Acknowledgements).

Line 197 - 198

HCP interviews and focus groups were conducted by FR and KON (PhD researchers on the team at the time – see Acknowledgements) between April 2016 and February 2017.

Supplemental File 1 shows the interview guides were part of a published realist evaluation protocol. If this is the same study, could you make reference to this here? This might help the reader understand which paradigm, theorist, and type of data analysis framed the methodology in this section. Or, could you clarify whether the main analysis was TDF and a systematic review used for coding?

We have clarified this in the methods

Line 202-207

HCP interviews were conducted as part of a broader realist evaluation to understand the implementation of the national clinical programme for diabetes, including the establishment of a national DRS programme [74]. As such, the topic guide was informed by attendance patterns and initial theories about how the DRS programme was working. It also included open questions to elicit HCPs’ experiences of engaging with the national DRS programme, for example, barriers to, and facilitators of, the registration process (Suppl. File 1).

Line 210-214

The analytical approach for this intervention development study did not follow the principles of realist analysis. Instead, the deductive analysis was directed by the Theoretical Domains Framework (TDF), and informed by a coding structure developed as part of a recent systematic review of screening attendance (Suppl. Table 1) [26] was used to code interviews to identify the barriers and enablers to the target behaviours; and to guide the choice of intervention components [75].

Please clarify if the group discussions were with the research team and general practitioner, or others (line 239).

We have clarified this now:
The final components were decided by a subgroup of the research team (FR, SMH, PMK, SMS) and a GP collaborator (MM) based on the APEASE (affordability, practicability, effectiveness, acceptability, side effects, equity, sustainability) criteria. Acceptability and practicability criteria were populated with findings from consensus meetings using a process informed by previous studies which utilised consensus methods [81] (Box 1). The effectiveness criterion was based on a rapid evidence review of different approaches to improve screening (e.g. text/letter/phone reminders and messages, educational materials, brief interventions and narrative leaflets) (see Suppl. File 3 PubMed search strategy). Remaining criteria were based on group discussions among the subgroup of research team and GP collaborator.

The first time the title of the intervention is introduced is line 256. Please consider introducing the reader to the name closer to the beginning of the manuscript for flow. We have amended this to introduce the study name in the Design section.

Line 158

The IDEAs (Improving Diabetes Eye screening Attendance) intervention, was developed by combining theory, stakeholder involvement and evidence [62, 63].

Consider moving the system-level factors that need to be addressed to the Limitations section rather than the Implications section (lines 492 - 501).

We have moved this section to the Limitations.

Duplicate "along with" in line 144.

This has been amended.

Consider removing square brackets in line 287 and using "such as getting time off work."

This has been amended.

Already introduced the IDEAS acronym, so no need for line 351 in brackets.

This has been amended.


This has been amended.

Representativeness of sample. Was gender and sex taken into account?
Patients were sampled purposively for the interviews according to screening status and not by demographic factors. Similarly, HCPs were sampled according to their role and region of Ireland, not other demographic factors.

To identify barriers and enablers, we analysed existing qualitative data collected as part of a study to understand patient and professional experiences of DRS among other diabetes services. Patient interviews were conducted by MT (July 2014 and January 2015) (see Acknowledgements). Participants were purposively sampled from the list of audited patients according to screening status (i.e. attenders, non-attenders, non-consenters) defined according to the audit. Participants were not sampled by other demographic factors.

HCP interviews and focus groups were conducted by FR and KON (PhD researchers in the team at the time – see Acknowledgements) between April 2016 and February 2017. HCP participants were purposively sampled according to their role and region of Ireland, not other demographic factors.

Reviewer #2

The authors report a largely qualitative study, in which they have used theory and coproduction methods to develop a set of implementation strategies to drive uptake of diabetes retinopathy screening. The study is well written, appears to have been conducted well and it is certainly within the scope of the journal and the interests of the readership. I do not have any major reservations about the study. However, I wonder whether the positioning of the study could be improved - as follows. At present, the study takes the perspective of low uptake of DRS and how that could be improved. The methodology subsequently applied is informed by a number of methods and frameworks that, in effect, demonstrate the usefulness of applying systematically such frameworks to the development of implementation strategies, for the latter to have a good chance of being effective and implementable. The discussion then offers some reflection to this effect.

A hidden point in this approach is that DRS in this context could be seen as a case study: there is a core message here in terms of how they theory and methods have been applied - which in my view is worth stressing and highlighting far more in the paper, especially in the early positioning of the study. Simply put: the study has a number of elements to be highlighted from the point of view of the methods of implementation science and coproduction that are unrelated as such to the clinical service context - and these in my view are rather implicit in the discussion and absent from the introduction.

For example: how does one reconcile the top down, theory driven approach of the TDFT and CFIR with the bottom up approach of a ToC? Are there tension is what emerges from interviews
that perhaps does not fit with TDF categories - and the like. Highlighting these could make the study far more readable and citable by implementation scientists working in entirely different clinical services.

So what I would recommend to the authors is to expand and/or rebalance the introduction to develop the argumentation about the need for theory driven and at the same time coproduced implementation strategies.

And likewise to develop a more theory-relevant reflection in the discussion, to complement their commentary re DRS, such that when reading this paper the reader walks away with some reflection re the role of theory in intervention development beyond diabetes.

I would also suggest that the authors consider having such a theory-informing aim as the secondary aim of their study, as I think such an aim is actually well attained.

Thank you for this suggestion. We have made a number of revisions to the manuscript to rebalance the intro and discussion and make the broader relevance to intervention development more explicit.

Introduction

1. In the Introduction, we have integrated the information highlighting the role of theories and frameworks into the paragraph specific to screening interventions. We have done this in order to establish the value of DRS as a case study:

Line 129-135

However, a recent Cochrane review found while interventions target some important barriers, they incorporate a narrow range of behaviour change techniques, with ‘missed opportunities’ to target some of the individual, social, cultural and environmental barriers and enablers of screening attendance [56]. In addition, the effects of interventions vary widely, and this variation remains largely unexplained [41]. Few studies are explicit in terms of the frameworks and theories used to guide intervention development [13, 45, 57]. Therefore, DRS is one clinical service which would benefit from a more systematic, theory-based approach to improve implementation.

2. We have expanded and reframed the subsequent paragraph in the Introduction to address the reviewer’s comments about theory and co-production, to better position the paper:

Line 137-146

There is ongoing uncertainty about the best approach to develop and tailor interventions [31, 58, 59]. Despite mixed evidence on the contribution of theory to intervention effectiveness [60, 61], it is a central part of many approaches to developing interventions. User involvement is recommended as another key component [62, 63] to tailor the content of interventions to context
(i.e., primary care setting) [31] and align with stakeholder preferences [64]. Despite recognition that these elements are important, the challenge is how to combine these elements, for example, it is often unclear how development moves from theory to decisions about intervention content, format and delivery, and what role stakeholders play in this step [65]. There is a need for case examples which clearly outline all steps of the development process, in particular how to utilise theory while also eliciting and integrating the perspectives of end users, drawing on elements of coproduction.

Discussion

We have highlighted the broader relevance of this study in the first paragraph of the Discussion:

Line 441-446

To improve DRS uptake, our intervention will target both professional behaviour (using practice briefing, training, reimbursement, audit and feedback, and prompts) and patient behaviours (using GP-endorsed reminder messages and information leaflet). Our process outlines how to develop a theory-driven intervention while involving stakeholders throughout and integrating their perspectives and preferences.

We have expanded the Implications section to more fully reflect on, and explicitly refer to, specific challenges and lessons which we feel are relevant to intervention development beyond diabetes. We have structured the section accordingly so that there are clear, distinct paragraphs relating to the following:

1. Challenges of applying the TDF/BCT structure
2. Challenges of using coproduction (i.e. tensions between theory informed suggestions and those suggested by stakeholders).
3. The utility of using both TDF and CFIR
4. The potential and feasibility of applying the APEASE criteria

Line 531-535

We identified a number of challenges during the development process which have broader methodological relevance for implementation science, namely: challenges with respect to applying the TDF/BCT structure; challenges using coproduction (i.e. tensions between theory-informed suggestions and those suggested by stakeholders); the utility of using both TDF and CFIR, and; the potential and feasibility of applying the APEASE criteria systematically. These issues are relevant for those developing interventions beyond the DRS context.

Line 538-556
While application of the TDF and subsequent mapping to BCTs was useful to identify theory-informed approaches to target barriers and facilitators, this process was not always straightforward. In some cases, the TDF/BCT structure needed to be applied flexibly. For example, HCP interviews were used to inform the ‘Skills’ domain at the patient level (i.e. patients were not always able to contact or register with the screening programme due to poor IT literacy). Sometimes, multiple TDF domains applied to a specific barrier or facilitator, whereupon multiple domains were applied. For example, patients who recognised screening as a routine part of their diabetes care would attend; this facilitator could be coded as ‘Memory and decision processes’, ‘Knowledge’ or ‘Goals’. There were instances where BCTs deemed appropriate to target a barrier or facilitator did not necessarily map to the corresponding TDF domain. Drawing on the input of researchers and academic GPs, in conjunction with an evidence review, was key to enable the TDF/BCT framework to be applied flexibly and determine which operationalised BCTs ‘made sense’. Mapping to TDF domains yielded several possible BCTs, but not all BCTs were relevant, applicable or appropriate for the behaviour in question and context of interest. In this scenario, we found the stepped process of stakeholder involvement was essential to move beyond the TDF/BCT matrix, and to help us make decisions about intervention components which would not be worth pursuing based on acceptability and feasibility concerns. Ultimately while it was useful to draw on theory and the structure afforded by TDF/BCT, in order to ground our initial intervention components and select the content and delivery mode relevant for the specific context (i.e. primary care), it was crucial to bear the real world context for the intervention and the users in mind.

Line 559-584

Our approach also highlights potential challenges of utilising coproduction in intervention development. To involve people with diabetes and HCPs we used a two-stage consensus approach, collecting both quantitative and qualitative data and using a validated instrument to assess acceptability and feasibility [80]. To avoid overly influencing our participants, discussions were semi-structured. This allowed them to reflect on the acceptability and feasibility of a long list of potential operationalised BCTs. However, this format also presented tensions at different steps of the process. Firstly, some end users made suggestions which fell outside of study scope or were not evidence-based; this may have reflected the fact participants were not constrained by a more structured format such as Nominal Group Technique or Delphi [105]. As suggested by Powell et al., there is value in presenting stakeholders with evidence-based options and asking them to supplement these based on their own expertise [31]. Deciding how to manage conflicts between, and prioritise, different sources of knowledge (e.g. evidence review vs. tacit knowledge and preferences of stakeholders) is recognised as important during intervention design [65]. However, there is little guidance about how best to balance these different sources. Secondly, integrating the contributions of the different groups across our process was a key challenge, particularly as professional and patient preferences did not always align. Ultimately we resolved to make evidence-based decisions, incorporating a final check to ensure we addressed salient theoretical domains (barriers and facilitators), and weighing the contributions of patients and professionals according to the nature of their feedback, for example, professional feedback on issues of feasibility (e.g. reminder delivery mode), and patient feedback on issues of acceptability (reminder messages) were given more weight. Given some of the challenges outlined by the current study, future studies should consider how to structure and sequence user
involvement. This could be done by incorporating final ‘checks’ of user suggestions to check whether these are in line with theory or existing evidence or seeking the input of users on theory-informed intervention elements. Future studies should consider how best to strike a balance between: a) thoroughness of end-user involvement whereby open selection from a long list of suggestions gives users more scope to shape and co-create the intervention, and; b) the efficiency of using a more structured approach such as providing specific examples of interventions and asking for feedback [106].

Line 588-591

A plethora of frameworks exist for intervention development and investigating behavioural influences [59, 107]. Our study drew on the relative strengths of different frameworks for different purposes. As in other studies [71], we found utilising CFIR together with the TDF useful to elaborate on implementation determinants in the outer and inner setting which fall within the TDF domain ‘environmental context’, and help translate barriers and enablers into practical approaches to implementation [108]

Line 597

Our study demonstrates the potential and feasibility of applying the APEASE framework in a systematic way.

Aim

We have also expanded the aim:

Line 149-154

Our aim was to use a systematic process combining theory, stakeholder involvement and existing evidence of the effectiveness of interventions, to develop a multifaceted implementation intervention targeting both primary care HCPs and patients to improve the update of DRS. A broader aim of this paper is to provide a case study of how to systematically develop an implementation intervention drawing on both theory and stakeholder involvement, and to highlight some of the challenges and lessons inherent in this approach.

Conclusion

We reference this broader aim in the Conclusion:

Line 605-611

By systematically applying theory, collaborating with multiple stakeholders and reviewing the evidence base, we are confident we have developed an intervention which is more likely to be feasible to deliver in primary care and acceptable to both professionals and patients. We have
used the example of an intervention to improve DRS uptake to illustrate an approach to integrate theory with user involvement and some of the associated challenges. Our final intervention is designed to fit within the primary care practice workflow, leveraging the trusted professional-patient relationship and familiarity of local services to enhance implementation of a national population-level screening programme.

Abstract

We have made corresponding changes in the abstract:

Line 30-69

Background

‘Implementation interventions’ refer to methods used to enhance the adoption and implementation of clinical interventions such as diabetic retinopathy screening (DRS). DRS is effective, yet uptake is often sub-optimal. Despite most routine management taking place in primary care and the central role of health care professionals (HCP) in referring to DRS, few interventions have been developed for primary care. We aimed to develop a multi-faceted intervention targeting both professionals and patients to improve DRS uptake as an example of how to systematically develop an implementation intervention, by combining theory, stakeholder involvement, and evidence.

Results

We identified potentially modifiable target behaviours at the patient (consent, attendance) and professional (registration) level. Patient barriers to consent/attendance included confusion between screening and routine eye checks, and fear of a negative result. Enablers included a recommendation from friends/family or professionals and recognising screening importance. Professional barriers to registration included the time to register patients, and a lack of readily available information on uptake in their local area/practice. Most operationalised BCTs were acceptable to patients and HCPs while the response to feasibility varied. After considering APEASE, the core intervention, incorporating a range of BCTs, involved audit/feedback, electronic prompts targeting professionals, HCP-endorsed reminders (face-to-face, by phone and letter), and an information leaflet for patients.

Conclusions

Using the example of an intervention to improve DRS uptake, this study illustrates an approach to integrate theory with user involvement. This process highlighted tensions between theory-informed and stakeholder suggestions, and the need to apply the TDF/BCT structure flexibly. The final intervention draws on the trusted professional-patient relationship, leveraging existing
services to enhance implementation of the DRS programme. Intervention feasibility in primary care will be evaluated in a randomised cluster pilot trial.