Author’s response to reviews

Title: Feasibility of an implementation intervention to increase attendance at diabetic retinopathy screening: protocol for a cluster randomised pilot trial

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Some of the additional files contain important feasibility information and should be included in the text rather than be an additional file - files 1 and 6 and possible 5. Please include files 1 and 6 in the main text and check all additional files are referred to from within the text when reordered.

Additional files 1, 5 and 6 have now been included in the main text as Table 1, 3 and 4 respectively. Remaining additional files 1-3 have been reordered.

Please provide an expected sample size number for one average practice in sample size section.

We have added this detail:

Line 327

Eight practices will be recruited. Based on previous work conducted by the research team, within a practice it is expected that 20% of patients will not be registered. Of those who are registered, it
is expected 34% will not have consented to the programme, and 3% will not have attended. Therefore, assuming an average practice size of 1200 patients and a 5% prevalence of type 2 diabetes, at each practice it is estimated that 12 patients would not be registered for the screening programme (20%). Of the 48 patients registered, 18 would be eligible (17 would be non-consenters (34%) and 1 would be a non-attender (3%)).

Line 129: This is a very comprehensive programme of research. However, I am not from Ireland and I would appreciate more contextual detail on RetinaScreen. For example, where do people go to have their eyes checked when prompted via RetinaScreen? Do the authors know the proportion of people with diabetes who are registered with the programme? Are GPs trained (and funded) to screen for diabetic retinopathy themselves?

We have added the following detail:

Line 130 – 146

In Ireland, a national DRS programme (RetinaScreen) was introduced in 2013 to offer free, regular diabetic retinopathy screening to people with diabetes. All people with diabetes who are older than 12 years old are invited by letter to participate in the programme [48], after which they provide consent for the programme to hold and use their contact details and receive an appointment. People have their screening appointment at one of the designated screening centres in variety of community locations, including high street opticians, community health care centres and community hospitals. Some screening locations based within primary healthcare centres, are co-located with other services, including general practice. In Ireland, GPs are not trained and funded to screen for DR. Following screening, participants who require further investigation and treatment are referred to one of seven treatment clinics nationally. The national programme works in conjunction with photography and grading providers (EMIS Care and Global Vision), to deliver the service. There is no national register of people with diabetes. The initial RetinaScreen register was populated in 2012 by using information from national health schemes. Those who were not captured by this method have to be added to the register by a GP or by other healthcare professionals involved in diabetes care. It is estimated that between 5.6 and 5.8 per cent of the population of Ireland have diabetes and this would equate to approximately 200,000 patients having the condition across Ireland. Based on figures reported by the national programme, as of December 2017 there were 164,569 men and women on the register, approx. 82% of the estimated population. Figure 1 illustrates process of consenting and attending to the programme.

Line 165: Individual-level inclusion / exclusion criteria for the study are:

* Aged 18 years or over
* Have diagnosed diabetes (type 1 or type 2)
* Are eligible to attend the national screening programme but have not attended the screening service (i.e., recently in the past 12 months or ever)
Individuals will be excluded if they have attended the DRS programme or are known to be having retinopathy treatment.

Can the authors please justify why people who have previously screened but who have not attended within guidelines (i.e. in the past 12 months) are not included in the feasibility study? Many retinal screening intervention evaluations have included 'lapsed' individuals (e.g. Anderson et al 2003; Basch et al 1999, Gabbay et al 2006; Lafata et al 2002; Lian et al 2013, Pizzi et al 2015; Prela et al 2000; Walker et al 2008, Weiss et al 2015, Zangalli et al 2016; Maliszewski et al 1988) and arguably, knowing whether the IDEAs intervention improves DRS return for this group is equally important as initiating uptake for those who have never screened.

We agree with the reviewer. Lapsed individuals are eligible to receive the intervention. We have revised the wording to make this clearer.

Line 171
Inclusion criteria include:

- Aged 18 years or over
- Have diagnosed diabetes (type 1 or type 2)
- Are eligible to attend the national screening programme but have not attended the screening service (i.e., recently in the past 12 months or ever)

Individuals will be excluded if they have attended the DRS programme recently (i.e., in the last 12 months) or are known to be having retinopathy treatment.

Line 186: The IDEAs intervention appears to be well-designed and grounded in both evidence and theory. The DRS literature demonstrates that those who have not engaged with the behaviour often face an accumulation of barriers. Cultural and language barriers are major impediments to uptake of DRS, yet I do not see reference to accommodating culturally and linguistically diverse populations within the intervention. For example, are the printed materials available in other languages, or will the practice nurse selected to provide verbal reminders (Line 268) be selected on their cultural and linguistic 'fit' with the clinic population?

At this stage the intervention has not been made available in other languages. Based on the findings from the current study, it may be necessary to tailor the intervention to population subgroups to improve ‘fit’. We acknowledged this in the intervention development paper, and have amended the Discussion section as follows:

Line 556 - 571
The current intervention was developed through a systematic multi-stage process combining theory, evidence, and consultation with multiple stakeholders. Components found to improve uptake of retinopathy screening [38, 43, 72] and cancer screening [73-82], include audit and feedback [83], patient [73, 76, 77, 79, 84-91] and physician [38, 72] reminders, the use of trusted sources to deliver messages [37, 73-75], and key information leaflets [74, 81, 82]. Our intervention comprises these strategies. As mentioned, successful delivery of the intervention in
general practice may be affected by several factors, including workforce shortages [92-95], workload and time constraints [96], and other demands on the service. Furthermore, the recent introduction of remuneration for GPs in Ireland to provide structured care to certain patients with diabetes (i.e., only those holding a means-tested general medical services (GMS) card; a public insurance scheme which entitles cardholders to free access to their GP) [20], could mean patient groups are managed differently in general practice according to their healthcare cover. We acknowledge this intervention does not address language barriers and may need to be adapted to improve cultural and linguistic ‘fit’ with some populations [56]. As part of the process evaluation we will examine fidelity and adaptations and whether patients considered the intervention appropriate for them.

Line 268: I am surprised by some of the scripted messages in the verbal reminders. For example, given the acknowledged confusion between standard eye check and screening for DR, I would have expected that the first message would check participant understanding of the role of the RetinaScreen programme. I would also suggest that the first message be in question format to minimise risk of defensive reaction from people who have resisted taking part to date. For example: "I am from…xxx…clinic. Are you aware of our national RetinaScreen programme?"

We agree with the reviewer. The final script does include an optional prompt which health care professionals can use if they feel the participant is not familiar with the RetinaScreen programme. For the feasibility study we will focus on adaptations. This will include enquiring about reactions to the messages among patients to determine whether there was a defensive reaction. For clarity we have amended Additional File 2 (previously Additional File 3):

Our records show that you may not have participated in diabetes eye screening recently with the national RetinaScreen programme. Do you know about Diabetic RetinaScreen? RetinaScreen is the national diabetes retinopathy screening programme which offers free, regular retinopathy screening to people with diabetes.