SAGE Research Methods Cases
Medicine & Health
Submission for Consideration

Case Title: Applying behavioral insights to real-world letter invitations: A randomized controlled trial testing for the effect of personalization and risk frame messaging on NHS Diabetes Prevention Programme uptake

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Postgraduate

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Economics and Political Science, a CFA Charter from CFA Institute and degrees in both Finance (B.Comm) and Psychology (B.A.) from the University of Calgary. As a behavioural scientist, Madeline researches the impact of mindfulness meditation on financial decision-making, and works in areas spanning private, public, and not-for-profit organizations.

Dr Laura J. Brown is a Postdoctoral Fellow at the Department of International Development at London School of Economics and Political Science. Laura holds a BSc in Biological Anthropology from the University of Kent, an MSc in Reproductive & Sexual Health Research and a PhD in Epidemiology & Population Health (Demography), both from the London School of Hygiene & Tropical Medicine. Laura has previously worked in Public Health England's Behavioural Insights Team, where she conducted the analysis for behaviorally-informed public health trials on the topics of food environments, obesity, diabetes, and HIV testing. Laura ran the analysis for the Diabetes Prevention Programme letter trial discussed in this case study.

Dr Tim Chadborn is Head of Behavioural Insights and Evaluation Lead for Public Health England, establishing and leading a team to undertake robustly-evaluated interventions and provide advice on the application of behavioural economics, psychology and evaluation to public health. With about 25 years of experience he has previously worked in the UK with the Department of Health and Health Protection Agency and internationally in a partnership between Harvard University and the Ministry of Health in Botswana and with the London School of Hygiene and Tropical Medicine. He is a member of the Cabinet Office's Trials Advisory Panel, the Cross-Government Evaluation Group, the Cross-Government Behavioural Insights Network, and Vice-President of the UK Evaluation Society.

Dr. Jet G. Sanders is a professor in Behavioural Science at the department of Psychological and Behavioural Science, at the London School of Economics and Political Sciences (LSE). Jet holds a PhD and MRes in experimental psychology at the University of York and an M.A. from the

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Published Articles

Sanders, J.G., Brown, L., Quiafe, M., Chadborn, T. (in preparation) Applying behavioural science to letters inviting pre-diabetic's participation in the UK national diabetes prevention programme: A randomized controlled trial of the effect of risk frame messaging on NHS diabetes prevention programme uptake. Intended for BMC Public Health

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Abstract

In this case study we summarize a large-scale randomized controlled trial (RCT) conducted by Public Health England Behavioural Insights (PHEBI). The RCT compared which of two invitation letters was most likely to increase uptake of the NHS Diabetes Prevention Programme (NHS-DPP) amongst patients at high risk of developing diabetes. These patients received an invitation letter to attend the NHS-DPP, as a means to introduce lifestyle changes which reduce their likelihood of developing diabetes in the future. The aim of this research project was to design the invitation letter using behavioral insights and test its effectiveness for 1) uptake and 2) adherence to the NHS-DPP. This case study explains in detail how the research was undertaken

and introduces behavioral science frameworks that facilitate the design, testing and ultimately implementation of behavioral interventions in the context of real-world preventative health care.

Key words: behavioral science, diabetes prevention, frameworks, NHS, diabetes prevention programme, invitation letters, uptake and retention.

Learning Outcomes

By the end of this case study, students should be able to:

- Explain the potential of behavioral science in real-world preventative health care.
- Navigate the uses of behavioral science frameworks in a real-world context.
- Apply behavioral science frameworks to intervention and experimental design.
- Recognize challenges associated with real-world behavioural science experiments and identify the necessary steps to overcome them.

Case Study

Project Overview and Context

Why diabetes prevention?

Type 2 diabetes is a serious health condition that causes the level of glucose in the blood to become too high (NHS, 2019). In addition to the health risks (Public Health England, 2018a), there are significant costs associated with type 2 diabetes – in the U.K. type 2 diabetes related expenses account for approximately 9 percent of the annual NHS budget (NHS, 2019). Currently, there are about 3.4 million people in England suffering from type 2 diabetes, with over 200,000 new patients diagnosed each year (Diabetes UK, 2019). Type 2 diabetes is linked to social and environmental factors, and is largely preventable through lifestyle changes (Knowler et al., 2002). In order to help patients at risk of developing type 2 diabetes make such changes, the NHS has in recent years launched the NHS Diabetes Prevention Programme (NHS-DPP; (NHS, 2016)). The program was rolled out with a first wave of 27 areas in the UK (covering half of the British population) and is now available nationwide with the ambition to support 100,000 people per year, free of charge (NHS, 2019). However, a service being available doesn't always mean people take it up: while the program has a good uptake, with 53% (NHS, 2016) there is still plenty of room for increased adoption. People often don't know they are at risk of developing diabetes before it is too late and even if they know, they don't always want to change, or know how. A key question is therefore: how do we support people to take up this service?

Why invitation letters?

One means by which at-risk patients are invited to partake in the program is through an invitation letter from their general practitioner (GP). This letter informs them of their risk and of their eligibility for the program. What is written in the letter is therefore an important gateway towards patient uptake and (hopefully) completion of the program. When a patient reads the letter, it could result in taking action or it could not. If action is taken, this could be the first step towards lifestyle changes allowing the patient to prevent the development of diabetes and all its

associated consequences. In this project we focused on developing a letter that would increase the likelihood of patients participating in the NHS-DPP once they had received their invitation letter.

Why use behavioral science?

In contexts like these, behavioral science looks to make a scalable impact by making small changes to an intervention (e.g. the invitation letter), based on an understanding of actual human decision making and behavior. Behavioral science is based on the premise that humans do not always behave rationally, but that they deviate from rationality in predictable ways. To provide a few simple examples: we are much more likely to pay attention to a message that comes from someone we trust than someone we do not, regardless of the accuracy of the message (Martin & Marks, 2019); we don't like doing things that fall too far outside the norm for fear of social exclusion (Reynolds et al., 2015), and due to inertia (a fancy word for laziness) we are also much more likely to stick than switch, with important consequences for policies on pension savings (Thaler & Benartzi, 2004) and organ donation registration (Johnson & Goldstein, 2003). Incorporating these principles of non-rationality into the design of interventions can greatly improve their effectiveness. This application of behavioral principles can therefore have a disproportionately large effect on behavior, compared to the effort required to changing behavior directly. A fundamental principle, then, is to measure the effectiveness of the intervention by measuring what happens to actual behavior, as opposed to intentions to changing behavior (intention-behavior gap), as is the case in classic models of behavior change (Rhodes, 2017).

Why a real-world intervention?

Where possible, we attempt to test the effect of behavioral science principles within real-world environments. This is because its benefits are often situation-dependent (Dolan et al., 2012) and rarely directly replicate between laboratory experiments and real-world environments (Wiers et

al., 2018). So, the only way to really know what works is to test in-situ. As a bonus, if an effect is found it can be applied within that context right away. Applying behavioral interventions in the real world does, however, require significant amounts of preparation and coordination. If you want to apply behavioural science in real-world contexts, you – as the behavioral scientist – will likely design the experiment, but most often other people will be involved with implementing the intervention itself. This can be due to reasons of data protection or simply because other organizations run the operations closest to the population whose behavior you are researching day-to-day. For example, if you want to change London cycle lanes to increase cycling, you may design the experiment, but other groups will have to change the lanes, collect video footage of cyclists or other real-world cycle data before you can measure the impact. Depending on the complexity of an experiment, fieldwork often requires a project steering group, where stakeholders from involved parties are present, and must agree on the planned process of the project as well as be given regular progress updates.

Section Summary:

- Type 2 diabetes affects a large number of people and its onset can often be prevented with the help of lifestyle changes.
- The message in the invitation letter to a program aimed at helping people at risk of developing type 2 diabetes to make these changes may in some ways be responsible for the uptake and completion of such a program.
- Behavioral science applies an understanding of human irrationality to the design of more effective interventions in many contexts. Here we apply it to message framing in invitation letters for uptake and retention of a diabetes prevention program. Robust testing is a core

principle of behavioral science and, whenever possible, this should be done in a real-world context.

Partnering with a Real-World Organization

For most behavioral scientists, a crucial component to testing for the benefits of behavioral insights in the real-world is finding a real-world partner who is willing to run an experiment. Here we outline some of the key steps to establishing a partnership for a behavioral science research project.

STEP 1: Setting your own priorities

It is important to start with a clear set of priorities of your own. For behavioral scientists like us, who are interested in improving the public's health, this means: applying behavioral science in contexts 1) where it can make a difference, 2) where it may reliably increase public health and/or reduce health inequality, and 3) that are aligned with national public health goals, such as reducing anti-microbial resistance, air pollution, obesity, smoking or drinking, and preventing the development of chronic disease, such as diabetes.

STEP 2: Identifying a partner organization

Once priorities are set, there are broadly two routes for a researcher to approach real-world implementation: 1) reaching out to those who have access to relevant individuals (such as people who work at local councils, hospitals or supermarkets), or 2) by responding to a steering group's

specific request looking for behavioral science expertise. There are advantages and disadvantages associated with both approaches (see Table 1). In both cases, you ideally align with a partner who is already in agreement with some (if not all) of your set-out priorities.

	Advantages	**Disadvantages**
Reaching out to potential partners	More control over the intervention and testing if you have a choice between multiple interested parties Ability to form multiple partnerships and test the same idea in slightly different contexts to ensure generalizability of findings	Partners might need more convincing, especially in terms of the effort required for conducting a thorough behavioural trial There is often a significant up-front time investment before a potential partner is found (if at all)
Responding to a steering group's request	The partner is already on board with the application of behavioral insights, and may be more likely to put in the effort required for robust testing	The partner might have strong opinions on how to conduct the trial which limits the flexibility of the researcher in designing and testing potential interventions

Table 1 – Advantages and disadvantages of different routes to a research partnership

STEP 3: Matching stakeholder needs with own.

Once a partner is found, an important next step is to match stakeholder priorities with your own. Applying behavioral insights to increase uptake of the NHS-DPP for patients at high risk of diabetes through the development of a UK national template letter is well aligned with the priorities of Public Health England. For our reasoning see Table 2 (column 2).

This is not all that is required. As behavioral scientists, we often offer consultation, but to ensure that an intervention has the desired effect we need to test whether the insights have a measurable impact in a given context. This is often one of the hardest conversations to have with stakeholders as it requires organizations to meet specific criteria which allow for measurement,

such as is outlined in Table 2 (see Column 3) and sometimes requires additional time and money. As steering groups new to behavioral science have not always factored these costs into their budgets or timeframes, the suggested roll-out of a controlled experiment may be seen as introducing unnecessary additional cost and can be met with resistance. A successful collaboration (which turns a consultation on behavioral principles into a trial) therefore requires that all parties involved agree that the time, money and effort required to test for the intervention's effectiveness, is warranted.

Researcher prioritization criteria	**Evidence for project alignment from the literature**	**Project requirements for partnership**
Project must apply behavioral insights in a context where it can make a difference	Behavioral insights have previously been shown to increase uptake through messaging in letter invitations (Sallis et al., 2016)	Letters must be developed based on behavioral science principles and the effect on the NHS-DPP-uptake must be tested experimentally
Project must increase public health and reduce health inequality	Patients at high risk of developing diabetes are often in low socioeconomic status (SES) groups (Vinke et al, 2020), so if this intervention helps, it especially helps people of low SES, and thus contributes to reducing health inequality	Patients at high risk of diabetes have been identified and in case of test area selection, letters are sent to patients in low-SES areas
Project context aligns with national public health goals	Preventing the development of chronic disease, such as diabetes is a public health goal (Department of Health and Social Care, 2018)	The NHS DPP is evidenced to lower the patient's changes of developing Type 2 diabetes (Ashra et al, 2015)

Table 2: NHS-DPP: Matching Stakeholder Needs

STEP 4: Turning consultancy into a trial

Interdisciplinary, cross-sectorial steering groups often purposefully include people from different backgrounds: academic or applied experts, practitioners from industry; or managers from the private or public sector, each with their own goals and expectations of the project. Often, people will have little-to-no experience with behavioral science and thus convincing experts to spend

resources on thoroughly testing interventions requires their 'buy-in' that behavioral insights can indeed help to achieve their desired outcome.

To facilitate stakeholder 'buy-in', we offer a 10-20 minute introduction to behavioral science in one of the earliest steering group meetings with established behavioral science checklists such as MINDSPACE (Dolan et al., 2012) and EAST (Service et al., 2014) as applied to their context of interest. These checklists have been created to condense a body of literature in social psychology, cognitive psychology and behavioral economics into bite size chunks for non-behavioral scientists. MINDSPACE (Dolan et al., 2012) is an acronym which summarizes nine of the most commonly used behavioral principles: Messenger, Incentives, Norms, Defaults, Salience, Priming, Affect, Commitment and Ego and serves as a checklist for different types of behavioral interventions, whereas the individual letters of EAST (Service et al., 2014) stand for 'making things' Easy, Attractive, Social and Timely as four categories of behavioral insights. In initiating this project with our partners, we presented a set of examples along the MINDSPACE (Dolan et al., 2012) acronym with outcomes of studies in the preventative health care space similar to the problem of diabetes prevention (such as invitations to weight-loss programs, NHS screening or Health Check invitations).

We also tend to offer a list of context-specific suggestions should they be open to running an experiment, with a clear caveat that we would need to know more about the current context to be sure (see Figure 1 for an example).

Ideally, this approach instils enthusiasm amongst stakeholders. After all, we all want the intervention to be a success, and behavioral science is intended to make the intervention better. This is a good point to explain the most important part: *To test whether a behaviorally-informed intervention works depends on the specific context, so we have to run a randomized controlled trial to find out.*

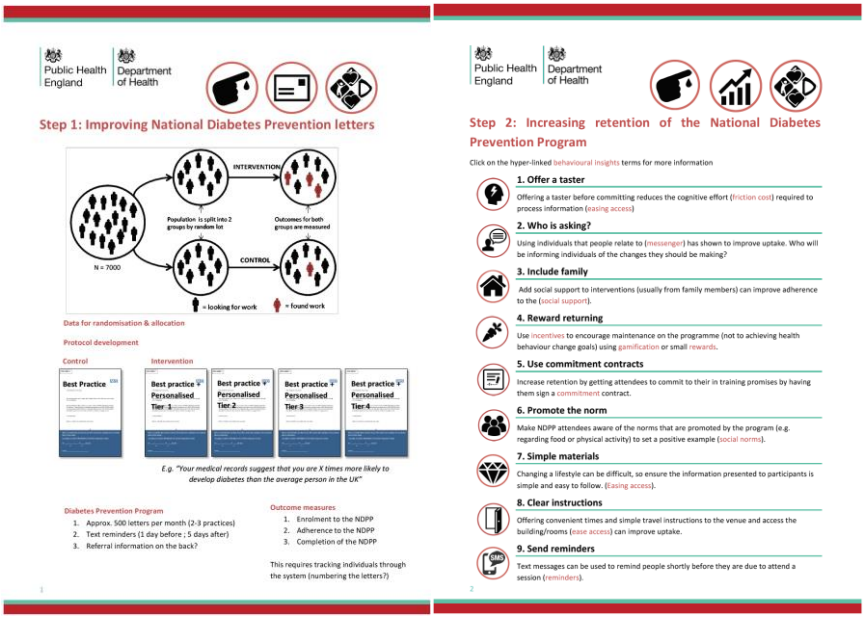


Figure 1- Example of suggestions provided to link behavioral science principles to the context of diabetes prevention. Randomized controlled trial to increase uptake through letter invitations (left); list of suggestions for alternative behavioral interventions (right; Public Health England, 2018b).

Section Summary:

- After setting your own research priorities there are two ways of bringing your research into the real world, either by contacting potential partners directly or by answering to a steering group's request.

- Two of the difficulties when working as a researcher with other partners include the alignment of interests and getting the partner's 'buy-in' to conduct a robust randomized controlled trial to test for the causal impact of the intervention.

Developing the Intervention

Typically, several methods are applied to behavioral science intervention design. Useful evidence-based frameworks for intervention design include:

1. The Nuffield ladder of interventions (Nuffield Council on Bioethics, 2007) describes various types of interventions from least intrusive (do nothing) to most intrusive (regulate or eliminate choice completely) with a number of different options between these two extremes. Some steps ‘up the ladder’ comes the idea of nudges which was applied in this study.

2. The Behaviour Change Wheel (BCW; Michie, van Stralen, & West, 2011) makes use of 19 behavioral change frameworks, which have been selected via a systematic literature review. At the core it identifies four promising sources of behavior to target with interventions: capability, opportunity, motivation and behaviour (COM-B). These sources are then surrounded by nine types of interventions to apply depending on the relevant COM-B analysis. Lastly, the BCW identifies seven policy categories that can support the implementation of the intervention.

3. The OECD’s BASIC toolkit (Hansen, 2019) to offers guidance to policy makers and behavioral practitioners on practical tools, methods and guidelines for the behavioural insight process from start to finish. BASIC stands for different stages of the project which are: Behaviour, Analysis, Strategy, Intervention and Change.

4. D.R.I.V.E. (Emmerling, 2018) was developed by Affective Advisory, and stands for Define, Research, Identify, Validate, and Execute to facilitate the holistic development of well-suited behavioral solutions in the context of organizational problems.

5. The Behavioural Change Taxonomy (BCT) is a hierarchical cluster of 93 techniques, distinct in method and developed to facilitate an agreed classification of intervention techniques for behavior change (Michie et al., 2013). It is a cross-domain structure and is used to specify the most granular aspects of behavior change intervention implementation, in both academia and practice.

These frameworks offer guidance to behavioral scientists working with stakeholders who have first-hand knowledge of the target population and the intervention point (Emmerling, 2018, Define and research). To provide some examples of the types of questions that are important to find answers to: How are letters currently being sent? How much input do GP practices have? By what method do GP practices invite patients to the NHS-DPP? And how can you trace people having received one letter or another? In summary, they offer support in identifying the best intervention and finally, the best implementation strategy (Nuffield Council on Bioethics, 2007; Michie, van Stralen & West, 2011) and behavioral outcome measurements (Emmerling, 2018: Execute). Finally, when the results are written up for publication the BCT (Michie et al., 2013) can be used to map the behavioral principles applied to relevant literature.

Section Summary:

- There are a number of established behavioral science frameworks that can help researchers with the design of a behavioural intervention.
- Some of these frameworks are useful for illustrating to your partner organization how behavioral insights can be applied to change behavior, such as MINDSPACE and EAST. Others are better suited to understanding the target population or designing and testing the

intervention itself, such as the Behaviour Change Wheel, D.R.I.V.E. and the Behaviour Change Taxonomy.

Research Design

The central goal of this study was to design and test an intervention letter that would increase the uptake of and adherence to the NHS-DPP. As a starting point we used an adaptation of the 'best-practice' NHS Health Check invitation letter, which had been previously tested for effectiveness in NHS Health Check uptake (Sallis et al., 2016). Key behavioral features of this letter included its short and direct nature and a tear-off slip prompting the recipient to write down relevant appointment details (time, date and location). We used these same principles as a baseline or *control* letter (Figure 2) in this trial. In addition, we argued that being at high risk of diabetes is hard to understand (as measured with the not-well-known HbA1c value in your blood; Farmer, 2012) and that it can be scary to learn that you are at risk, which may result in avoidant behavior (Rimal & Real, 2003). Thus the *treatment* letter (see Figure 3) added a personalized display of the patient's risk level to make the meaning of their HbA1c value easier to understand, and a self-efficacy statement (D'Souza et al, 2017) aimed at empowering the reader to take action in spite of the bad news.

The hypotheses of the study were primarily that the treatment letter would:

- increase number of calls made by patients to sign up for the NHS-DPP;

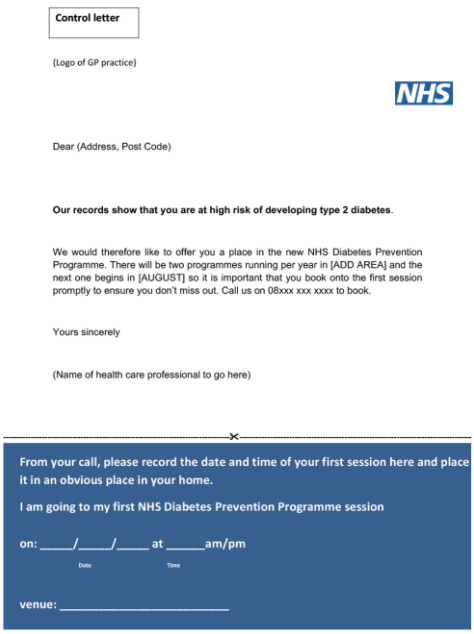
And secondarily that it would:

- increase attendance of the first session of the NHS-DPP;
- increase the retention rates of the NHS-DPP;

- and increase the completion rate of the NHS-DPP.

To test these hypotheses and compare the effectiveness of the two letters, PHEBI conducted a two-armed randomized controlled trial (Cowen et al., 2017). This means that the at-risk patients were randomly allocated to either the control or the treatment group of the trial. The control group received the *control* letter and the treatment group received *treatment* letter. To test any causal impact of the intervention a randomized controlled trial is the optimal and only reliable way to know whether time caused the change or whether the intervention did (Bhide, Shah, & Acharya, 2018). As it is impossible to observe two alternative paths simultaneously, we have to find another way to infer the intervention's causality. Allocating participants within a sufficiently large sample randomly between the treatment group and the control group allows researchers to mimic two groups that on average do not exhibit any systematic difference, in order to compare them reliably. Note, of course, that RCTs do not specifically determine *why* the intervention worked or did not, and RCTs may not always be the best or most practical solution in the given situation. In some cases, other evaluative methods may be more appropriate.

In order to test if the intervention had a statistically significant impact, uptake in the treatment and control group were compared and differences in attendance and adherences were analyzed using appropriate regression models. While the main variable of interest was the initial uptake of the NHS-DPP by June 2018, the study also analyzed the likelihood of patients attending the first session, and completing the 8-week program in its entirety. Using these outcome measures ensured that the overall benefits of an increase in initial uptake are not cancelled out by reduced participation or completion (Truelove et al., 2014).



Control letter

{Logo of GP practice}

NHS

Dear (Address, Post Code)

Our records show that you are at high risk of developing type 2 diabetes.

We would therefore like to offer you a place in the new NHS Diabetes Prevention Programme. There will be two programmes running per year in [ADD AREA] and the next one begins in [AUGUST] so it is important that you book onto the first session promptly to ensure you don't miss out. Call us on 08xxx xxx xxxx to book.

Yours sincerely

(Name of health care professional to go here)

From your call, please record the date and time of your first session here and place it in an obvious place in your home.

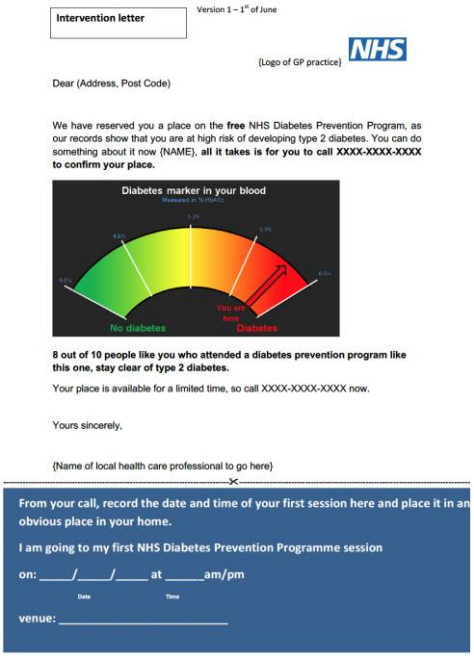
I am going to my first NHS Diabetes Prevention Programme session

on: _____/_____/_____ at _____am/pm

Date Time

venue: _____

Figure 2 - Template for NHS-DPP letter received by the control group.



Intervention letter

Version 1 – 1st of June

{Logo of GP practice}

NHS

Dear (Address, Post Code)

We have reserved you a place on the **free** NHS Diabetes Prevention Program, as our records show that you are at high risk of developing type 2 diabetes. You can do something about it now {NAME}, **all it takes is for you to call XXXX-XXXX-XXXX to confirm your place.**

8 out of 10 people like you who attended a diabetes prevention program like this one, stay clear of type 2 diabetes.

Your place is available for a limited time, so call XXXX-XXXX-XXXX now.

Yours sincerely,

{Name of local health care professional to go here}

From your call, record the date and time of your first session here and place it in an obvious place in your home.

I am going to my first NHS Diabetes Prevention Programme session

on: _____/_____/_____ at _____am/pm

Date Time

venue: _____

Figure 3 -Template for NHS-DPP letter received by the treatment group.

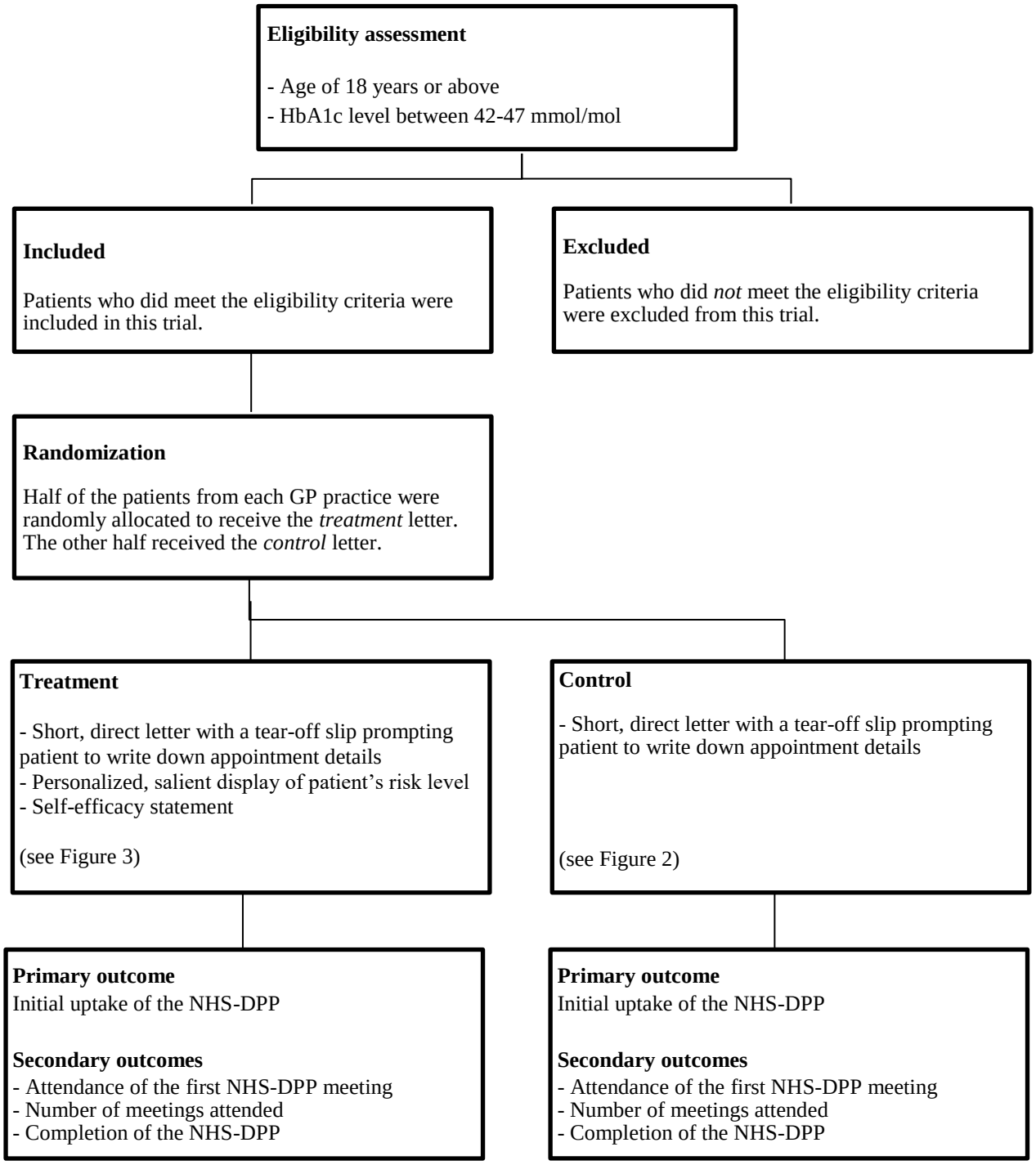


Figure 4 - Study flow diagram.

Section Summary:

- This study compared a control letter (based on the best-practice NHS Health check invitation letter) to a treatment letter (which added a personalized diabetes risk dial and self-efficacy statement).
- This study used randomization to decide which participants received the control and which received the treatment letter. This type of experiment is called a randomized controlled trial (RCT).
- Outcome variables of the study included the overall uptake difference between control groups (as per a phone call made to the NHS-DPP provider), attendance to NHS-DPP sessions, and completion of the program.

Research Practicalities

Ethics and consent

A number of steps were taken to ensure compliance with standard ethical protocol. As the patients were neither pre-informed of being part of a trial, nor debriefed following the intervention, the analysis was performed on anonymous data without any personal identifiers in order to safeguard their privacy. In agreement with our steering group, patients were only invited for the NHS-DPP if they met certain eligibility criteria: Participants needed to be 18 or over to be part of the trial, and have had an HbA1c level measurement between 42-47 mmol/mol (or 6%-6.4%) in the last year. In addition, all parties agreed that both patient groups received the same base information and opportunity to join the NHS-DPP, bar framing alterations which often vary from one GP practice to the next. Following internal agreement, the trial then went through an

NHS ethical board, was pre-registered and GP practices were informed via their Commissioning Group that this trial was taking place, and what this may mean for their GP practice.

Anonymization and linking data

As part of data protection, access to personally identifiable patient information (such as postal addresses or names) is only granted on a need to know basis. This means that the data needs to be anonymized in order for a researcher to have access to it. One important note regarding anonymization is that *full* anonymisation requires more than just removing identifying information (e.g., names, addresses). At PHE, in order for data to be considered fully anonymous, it needs to pass the "k3" test (NHS, 2013). This means that if the data is stratified according to all of the possible combinations of demographic variables (e.g., gender, age, ethnicity, GP surgery etc.), there must be *at least 3* patients in each combination (e.g., a minimum of three 75-year-old black men at GP surgery X, three 45-year-old white women at GP surgery Y etc.). If there are fewer than 3 patients for any combination of categories, the dataset cannot be considered fully anonymous.

Anonymization can also complicate the matching of data from different sources, such as patient information provided by a GP and patient information from a local NHS-DPP provider who may have different ways of storing data. In cases like these, stakeholders with access to patient data need to agree on a key (a set of numbers and letters that corresponds to each other) so that the data sets can be matched, whilst allowing personal data to be removed before the data is provided to the researchers. In this study, the NHS-DPP provider (Reed Momenta) and the letter sending company (iPlato) held the key. To help them with this process we asked stakeholders to provide mock data and provide a step-by-step protocol on how to create such a key and remove personal information. It is generally advisable to go through each step with mock data in advance to ensure that the protocol works as expected and that everyone understands the process.

Randomization

In the same vein, we provided a protocol to the company who sent the letters for allocating patients randomly. Here, we used a clustered randomization. This means that we did not take all patients and randomize them into the two groups, but instead used each of the 44 GP practices as an independent *cluster* of randomization. This approach takes into account that sociodemographic variables are more similar *within* than *between* GP practices, thus increasing the likelihood of capturing more similar types of patients receiving the control and treatment letter. Practically randomization into two groups includes four simple steps: 1) assign a random number between 0 and 1 to each patient in the sample using the RAND function in Excel; 2) identify the median number with the MEDIAN function in Excel; 3) order patients by this random number; 4) all patients above the median are assigned to the control group and the remaining patients are assigned to the intervention group. This process ensures an (almost) identical number of patients in each group by GP practice.

Section Summary:

- Working in partnership with real-world patient-facing organizations requires that all parties are involved in ethical procedures.
- Linking data with anonymized data sets can be complicated. Here several partner organizations were included in the data collection, analysis and randomization, which demanded coordinated efforts to link participant data in alignment with accepted experimental protocols.

Method in Action

In this section, we offer insights on some unpredictable elements of running a real-world behavioral science trial, and how one might navigate such unpredictability during or after the trial.

Data cleaning

Following the trial, there were a total of 4,689 entries in the dataset about the letters sent to patients and 1,309 observations in the dataset of the NHS-DPP calls received. This seemed like good news to start with as it was the sample size we had counted on. We had, however, not anticipated how many entries had to be manually removed: using the unique IDs and comparing these two data sets showed that only 1,271 observations matched across the datasets, whereas 3,826 were unmatched (408 from the NHS-DPP provider and 3,418 from the letter sending company). This is not unexpected: many of those who had received a letter would not go to the NHS-DPP, and perhaps some people were sent straight to the NHS-DPP by their GP without having received a letter invitation in the first place). But then, 230 more entries were deleted as duplicates based on the unique identifier and the NHS-DPP provider reference, and another 336 observations did not fit within the trial time period. There were also a number of duplicate entries where patients received both the control letter *and* the intervention letter. In 51 cases the call to the NHS was made was made after the intervention letter had been sent but before the control letter was sent. These 51 patients were thus allocated to the treatment group. In 47 cases, the opposite occurred, and patients called the NHS *after* the control letter had been sent but *before* the intervention letter was sent. Thus, these 47 patients were allocated to the control group and removed from the intervention group. As if that were not enough, a further 408 observations were removed as they were neither part of the control nor the treatment group. After this process, the remaining total sample size was down to just 3,650 patients (1,804 in the control and 1,846 in the treatment group). It is important to note that patient information safety was at no point

compromised by either the *order* of invitation letter send-out or by their *assignment* to the control or treatment condition.

Surprising results

The outcome of the study was unexpected: 28.9% of patients in the control group responded to the letter they had received compared to only 24.9% of participants in the intervention group (this difference was highly statistically significant, $X^2(1, N = 3,650) = 7.29$, $p = 0.007$). In other words, the likelihood of program uptake was 13.8% *less* for patients who received the intervention letter compared to those who received the control letter; our intervention did not 'work' as expected. It is important to note that this outcome was not the result of methodological 'flaws' in the application of behavioral principles; it simply shows that the control letter was better for increasing NHS-DPP uptake.

Of the 981 patients who called the NHS-DPP provider, 37.62% from the control group attended at least one DPP session, compared with 35.00% from the intervention group. This difference was *not* statistically significant ($X^2(1, N = 357) = 0.72$, $p = 0.395$). Patients attended six sessions on average which also did *not* vary statistically by trial arm ($t(355, N = 357) = -0.17$, $p = 0.866$). In other words, once patients had enrolled in the program, they were just as likely *to attend* and both groups attended a similar *number* of sessions.

We also looked to see whether ethnicity, age, BMI, or area-level deprivation (as measured by the Index of Multiple Deprivation) explained any of the observed effects of the intervention on attendance or adherence, but once they were controlled for this did not alter the results. Nor did controlling for clustering at the GP practice level.

Study limitations

One limitation of the study was that demographic data was only available for those patients who were in contact with the NHS-DPP provider Reed Momenta to uptake the NHS-DPP. It is not clear, therefore, whether demographic factors impacted the likelihood of calling the provider. Note that demographic factors were included in the attendance and adherence dataset and therefore integrated into the corresponding regression models. As mentioned above, their inclusion did not alter the headline results.

Another limitation of the study was its sample size. Because so many patients had to be excluded, it is a possible risk that the study was somewhat underpowered. However, if underpowered, we would not have expected the effect to go in the opposite direction of our hypothesis (as we did see here).

Section Summary:

- Following data collection, a lot of effort was required to 'clean' the datasets and ensure any entries that were duplicates were appropriately eliminated.
- The results of the study were unexpected: the intervention group had a *lower* initial uptake of the NHS-DPP. There were no statistically significant differences in persistence of attendance or average number of attended sessions between the groups.
- The study was limited by the availability of demographic information and a smaller sample size than anticipated.

Practical Lessons Learned

As per protocol

This trial showed us the importance of robust protocols which carries across different generations of project management. A common challenge to real-world trials is that they typically last 6 months to 12 months, if not longer. This trial faced heavy disruption as former stakeholders departed to other organizations and new project managers joined the steering group. In one instance the change of personnel meant putting in place an entirely new data sharing agreement, which delayed the project deliverables by a year. Individuals are often assigned to projects for a specific time period, but it is not unusual for projects to take longer than expected and it is important to agree in advance what happens if it does. To overcome the issue of handovers, we learned that each individual steering group member should be dispensable to the running of a project, and that we were to run as per protocol.

Defining 'success'

Within the academic community, there is an established precedent favoring positive or hypothesis-confirming results. The temptation is to present these studies as 'success', which neglects studies with unexpected or counter-intuitive results. This is known as 'publication bias' (Joober et al., 2012). However, unexpected results are very helpful in gaining new insight regarding drivers of behavior. These outcomes prompt further exploratory research, and some of the greatest insights and practical applications of behavioural science have been gleaned from systematic research which has had either statistically insignificant effects or even reverse/negative effects. Sound methodology to track these effects is important, because it

provides the evidence needed to understand underlying mediators or moderators in measured behaviors in order to refine interventions to be as successful as possible. So, while there may be temptation to publish only positive/expected results, it is crucial to draw attention to those other effects to determine which tools and techniques are most promising within a certain context - knowing what *doesn't work* is as important as knowing what *does*.

Section Summary:

- The best behavioral science frameworks for experimental/project design have common features which are heavily protocoled: problem identification, research collection, intervention design, structured roll-out, and debrief/result measurement.
- Publication bias favors 'successful' interventions but knowing what doesn't work is as important as knowing what does.

Conclusion

In an effort to increase the uptake of the NHS-DPP by patients at high risk of developing diabetes, a randomized controlled trial of a behaviorally-informed invitation letter was conducted in Southwark in cooperation with the National Health Service (NHS) and Behavioural Insights Public Health England (PHEBI). The use of behavioral science intervention frameworks was implemented to robustly structure the project from initial stakeholder engagement through to result measurement. Though the results of the study were unexpected, and in fact had a statistically significant negative effect, the study provided insight as to more and less effective message frames within this context, to be implemented immediately. This study and its outcome

also highlight the importance of thorough small-scale testing before rolling out any intervention to the wider population. By using empirical behavioral frameworks, this case study explains in detail how the behavioral intervention was designed and implemented in the context of real-world preventative health care. Practical steps and complications both during the trial and thereafter have been discussed.

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Classroom Discussion Questions

1) What are your research prioritization criteria and how do you find real-world partnerships which are aligned with your chosen criteria?

2) With MINDSPACE in mind, choose some of its elements and discuss ideas of how they could be applied to increase the uptake of the NHS-DPP.

3) How would you go about testing the impact of your proposed interventions? What do you think would be the best outcome measure for your intervention?

Multiple Choice Quiz Questions

1) Which of the following is *not* a necessary part of the experimental design process?

    a. Debriefing and reporting on results

    b. Collecting and analyzing relevant literature

    c. Conducting a laboratory pilot study - CORRECT

2) Which of the following is *not* a component of the MINDSPACE mnemonic of behavioural interventions?

    a. Ego

    b. Affect

    c. Social - CORRECT

3) Which behavioral framework can be of particular use at the stakeholder engagement stage?

    a. MINDSPACE

    b. EAST

    c. Both of the above – CORRECT

4) Why would you conduct a randomized controlled trial (RCT) to evaluate your intervention?

    a. RCTs are particularly powerful in determining a causal relationship between the intervention and the outcome. – CORRECT

    b. RCTs are very simple to implement, particularly in a real-world setting.

    c. Neither of the above.

Declaration of Conflicting Interests

The Authors declare that there is no conflict of interest.

Further Reading

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