

# **Efficacy of a nutrition and lifestyle digital intervention in women planning a pregnancy: a pilot randomised controlled trial in primary care.**

## **Start at the Beginning**

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## Pilot sites

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2. Homerton University Hospital NHS Foundation Trust
3. North East London NHS Foundation Trust

## Contents

Executive summary .....	5
What happened .....	5
What we learned .....	7
Conclusions .....	8
Background .....	9
The Role of Health Visitors.....	10
Smarter Pregnancy.....	10
Project Aims .....	11
Outline of the project phases .....	11
Study Methods.....	13
Governance approvals .....	15
Results .....	15
Recruitment .....	15
Consent Incident .....	15
Randomisation Incident.....	16
Baseline data collection .....	16
Table 1: Baseline characteristics of participants by randomisation arm .....	17
Follow up data collection .....	18
Qualitative Research .....	18
Participants Interview Findings.....	18
Reasons for Participation .....	18
Smarter Pregnancy.....	20
Recipes .....	21
Smarter Pregnancy for Men.....	22
Smarter Pregnancy Feedback .....	23
Smarter Pregnancy Improvements .....	24
Preconception Information Views .....	25
Identifying Target Population .....	25
Participant Views on Health Visitors.....	26

Participant Views on Further Study .....	27
Health Visitors Interview Findings .....	28
Participation.....	28
Setup .....	29
Recruitment .....	30
Training for Health Visitors .....	32
Women want Preconception Care Advice .....	32
Everyone Wants to be Involved .....	33
Discussion.....	34
Next Steps .....	36
References .....	37
Appendix I .....	38

## Executive summary

In 2015, responsibility for commissioning health visiting services transferred to local authorities. The same year saw the culmination of a government commitment to provide an extra 4200 Health Visitors, including 700 in London(1). As highlighted in the Five Year Forward View the future health of millions of children, the sustainability of the NHS, and the economic prosperity of Britain all now depend on a radical upgrade in prevention and public health(2). The challenge for commissioners of 21st century health and social care services, therefore, is the ability to shift funding upstream to make a difference, by preventing ill-health and prioritising resources to support this approach. These drivers led to the Department of Health (DH), awarding Health Education England (HEE) a grant to commission and coordinate three projects to evaluate the efficacy of the increased health visiting workforce in line with improved commissioning linked to public health outcomes. These evaluation projects are centred on a partnership with key stakeholders across North Central and East London and are also aligned to the DH six high impact areas for health visiting.

The projects are:

- **Preconception care** – Start at the Beginning
- **Maternal Mental Health** – Perinatal Mental Health Value Score Card
- **Supporting parents to manage minor ailments** – DIY health

These projects build on the Public Health Outcomes Framework and the NHS Outcomes Framework, as set out in 'The National Health Visitor Plan: progress to date and implementation 2014 onwards' (3), and they provide evidence of the unique contribution that health visitors provide to achieve those outcomes.

This report summarises the Start at the Beginning project, which worked with the Health Visiting service in East London. We outline the nine month set up phase (Jan 2014 – September 2014), the recruitment phase (October 2014 – June 2015), interview phase (June 2015–July 2015) and the analysis phase, ongoing.

## What happened

During this time, we obtained a license, from colleagues in the Netherlands, to use an interactive, m-health intervention (Smarter Pregnancy) designed to improve nutritional status and healthy lifestyle in the preconception period, and adapted it for use with women planning a pregnancy in East London. The m-health intervention is interactive in the sense that it asks registered participants to input personal data on dietary behaviours, smoking, folic acid intake and other health factors at specified time intervals, and then provides a personalised 'risk score' based on those factors. Feedback is provided in the form of tailored advice (e.g. where to seek support to stop smoking) and meal recipes. The aim of Smarter Pregnancy is to help women reduce their preconception risk score by improving nutrition and lifestyle before they become pregnant.

The adaptation work included translating all text from Dutch into English, adding further questions about health and lifestyle and - in response to our patient & public involvement (PPI) work - developing two forms of the Smarter Pregnancy for use in a pilot randomised trial: one form (the full m-health intervention) for the intervention group and another ('lighter' version) for the control group.

In conducting the pilot trial, we developed research partnerships with the Health Visiting service in the study sites (Homerton, Barts Health and NELFT) and with advisory groups including the study steering group and the Institute of Health Visiting.

Health visitors deliver care in a variety of settings; for this project the settings included home, hospitals, Children's Centres, GP practices, Health Centres and other community venues. The Health Visiting service was best placed to deliver this research as they play a key role in nutrition and family health with their client group. In order to approach women that may be planning their consecutive pregnancy key contact times were identified, however the subject was broached at all Health Visitor contacts.

Recruitment started slowly. Barriers to recruitment were discussed at a study steering group meeting in December 2014, which included the reluctance of some Health Visitors to want to be actively involved in the study. There were a range of reasons reported; their main concern was their capacity. It was then agreed that all members of the health visiting team could obtain informed consent, subject to GCP training and recruitment incentives were introduced. The rate of recruitment increased significantly in February and March 2015, coinciding with gaining the necessary permissions (ethics and R&D approvals) for the third study site (NELFT) to begin recruiting. By the end of the project we surpassed the recruitment target and had consented 310 women. In-depth interviews were undertaken with a subsample of participants and Health Visitors in order to explore their experience, opinions and the feasibility of the study.

Overall users enjoyed using Smarter Pregnancy and found the coaching and advice encouraging improving behaviours, with specific reference to increasing the fruit and vegetables in their diet.

Health Visitors stated that there was a need to involve their teams at an earlier stage of project development so that they can contribute and feel a part of the process. Health visitors also shared that there is a need for training in preconception health and care in order to provide advice for women planning a pregnancy. They also expressed that they were well placed to provide preconception care to their clients.

In the teams where the Call to Action increased workforce was yet to be fully realised, the project was not as well received. However in sites where the staffing levels had increased, the project did well and was well accepted by the Health Visiting teams.

## What we learned

We learned during the set up phase that adaptation of an m-health intervention and obtaining the associated information governance approvals is a demanding process (particularly when the internet server for the m-health intervention is outside the UK). We also found that rigorous testing of the tool should be undertaken to ensure appropriate translation has been achieved.

We learned from the PPI work that our original proposal – to randomise women to either the Smarter Pregnancy m-health intervention or to a paper information leaflet on preconception health – would be unlikely to succeed because nearly all women would want to be randomised to receive the Smarter Pregnancy tool. Accordingly, we developed a 'lighter' m-health intervention that is less interactive, requiring less frequent data input from participants, and giving less tailored feedback in terms of risk scores and recipes.

We learned the importance of developing strong partnerships with Health Visiting service from the outset, and fostering a sense of joint ownership of the project to reduce the perception of externally-driven work being imposed onto already heavy workloads, which hindered the progress of our study. We also learned that some Health Visitors regarded improving preconception health as a legitimate part of their role and welcomed the opportunity to take part in the study.

We learned the importance of ensuring that all staff involved in conducting research receives training in Good Clinical Practice (GCP). This became clear following a small number of incidents in which informed consent was obtained inappropriately. This prompted submission of an incident form to the study sponsor (UCL) and development of an action plan that was promptly solved. All members of staff involved were informed of the error and repeated their GCP training.

We also learned, through informal observation by a member of the research team supporting recruitment in the study sites, that women thinking of having another baby seldom receive any information from health care providers about preconception health and care. The few women who told us they had acquired some information about preconception health for a previous pregnancy had found this through looking on internet sites or from friends and family.

We found that we had a lower than anticipated follow up rate, which was largely due to the numerous steps involved in registration. After consent the users are required to register their details online via an electronic device, and then activate their profile from a personalised link sent to their emails. It was only after these processes that the Smarter Pregnancy tool begins with the baseline questionnaire. We found from the consent process to the baseline we had lost approximately 45% of our participants.

We learned from in-depth interviews that users were generally positive and liked using Smarter Pregnancy. They shared views of increasing the fruit and vegetable intake from the encouragement and advice from Smarter Pregnancy. They were positive towards having support in this pre-pregnancy period in their lives and the importance of being healthy prior to conception.

We learned that Health Visiting teams shared the desire to focus on preconception care as a part of their packages of care. However in some of the sites where the increased workforce Call to Action 2011-2015 was yet to reach trajectory, many teams felt they were working at full capacity and not able to take on additional work. It was also reported that many teams enjoyed taking part and to have the opportunity to influence preconception care as they felt they could have real impact on women's health, pregnancy and children, which all ties into their role.

### Conclusions

The Start at the Beginning Project has produced useful findings in exploring the feasibility of offering an m-health to improve preconception nutrition and lifestyles in women planning a pregnancy in East London. Important issues regarding obtaining informed consent and training in Good Clinical Practice arose and were immediately addressed. Qualitative in-depth interviews with users provided further insight as of their experience of taking part in the trial, and how we can improve the m-health intervention and take forward this work to improve preconception health and care. Interviews with the Health Visiting Leads highlighted improvements that can be made in the set up and progression of the study from a provider perspective.



## Background

The period before conception is increasingly regarded as important for the health of future generations (4). Many of the major threats to reproductive health are the same as those affecting public health more generally including obesity, smoking, alcohol, and diabetes and hypertension.

We recently completed a study of preconception health and care in England for the Department of Health Policy Research Programme (5). We examined over 4000 papers and 100 guidelines on preconception care, analysed data from two large cohort studies, surveyed over 1000 pregnant women & their partners at three London maternity units using a better measure (scored 0-12) of pregnancy planning (6) (the London Measure of Unplanned Pregnancy [www.LMUP.com](http://www.LMUP.com)) and conducted in-depth interviews with health professionals, and with women selected as high and low investors in preconception healthcare.

Key findings include:

- The literature on preconception care derives largely from observational research with pregnant women showing the adverse effects of various medical conditions and lifestyle behaviours on birth outcomes (e.g. diabetes, smoking and obesity). There are very few studies of the effectiveness of interventions starting before pregnancy on reducing risk factors or improving birth outcomes.
- Preconception interventions of established cost-effectiveness include counselling for folic acid supplementation and preconception care for women with diabetes, but again there are very few studies about how best to deliver effective interventions in clinical practice.
- Awareness of preconception health and care among health professionals and the public is generally low.
- Responsibility for providing preconception care is confused and delivery patchy.

However, from our antenatal surveys we found a significant association between health professional advice and positive behaviour change (reducing smoking, alcohol, adopting healthier diet and exercise) by women before pregnancy. A wealth of other literature shows the importance of maternal nutritional status for both mother and child including, for example, the association between maternal obesity and early cardiovascular mortality in the offspring (7) and a strong link between pre-pregnancy 'prudent diet' score and the degree to which women conform to infant feeding guidelines for their babies at 6 and 12 months (8), thereby indicating that patterns set in train before pregnancy carry over into the feeding of the infant.

## The Role of Health Visitors

Building on the findings of our policy based observational research, and the current evidence base, we proposed to evaluate, in women planning a pregnancy, the feasibility and efficacy of a web-based nutritional and lifestyle intervention to improve up preconception health. A key challenge is how to identify women who are planning a pregnancy. An opportunity to do this presents itself when women attend routinely to Health Visiting service for a developmental review at 8-12 months and 2.5 years after having a baby. We therefore proposed to ask women particularly at these points and at any Health Visiting contact, whether they are planning another pregnancy within the following 12 months, and if so, to invite them to take part in the pilot trial.

Preconception care is a part of the Health Visiting remit with specific reference to the Department of Health Early Years High Impact area 4: Healthy weight, healthy nutrition “Encouraging Healthy weight preconception and healthy pregnancy”. This study offers the opportunity for Health Visiting teams to focus on this target.

Health Visitors focus on community health which includes child health as well as health promotion and education. They work with families from pregnancy to age 5 covering the developmental milestones and physical checks. They have the unique opportunity to approach women and babies to have great impact on the family health. Whilst looking at the life-course approach, good preconception care has the ability to impact future health, which greatly aligns with Health Visiting practise.

## Smarter Pregnancy

Smarter Pregnancy is an m-Health interactive online based tool that aims to improve lifestyle, diet and nutritional behaviour in those planning a pregnancy through tailored personalised coaching. It was developed by a research group led by Dr Regine Steegers-Theunissen from Erasmus MC, Netherlands in Dutch. It has been successfully used in the IVF setting with both men and women.

After registration and activation of the tool, participants are randomised to either receive the full or light version of Smarter Pregnancy. The programme begins once the participant has registered and carried out the baseline screening, which includes their current lifestyle behaviours such as, BMI, age, nutrition and lifestyle risk factors, and continues for six months.

The programme then generates a personalised risk score with feedback and advice based on the answers provided. The questions are then repeated along with frequent coaching, tips and recipes.

The tool aims to reduce the individual risk score over time. Overall two main risk scores are generated. A Nutrition Risk Score (VRS) is composed of the three items - fruit, vegetables and folic acid. VRS ranges from 0-9 per participant, and a Lifestyle Risk Score (LRS) is composed of the of the two lifestyle habits (smoking, alcohol). LRS ranges from 0-3 per participant. In both instances 0 indicates a preferable lower risk.

## Project Aims

The purpose of this pilot trial is to determine the feasibility and efficacy of a nutrition and lifestyle digital intervention in improving preconception health in women planning a pregnancy who are attending Health Visiting services. The pilot trial will also provide key data to design a definitive trial of a preconception intervention to improve pregnancy and birth outcomes in women planning a pregnancy.

The primary objective is to compare a composite risk score, based on self-reported on dietary factors, smoking and intake of folic acid, between women randomised to receive more intensive preconception care health information via a web-based intervention in addition to a paper leaflet and women randomised to receive a reduced version of the web-based intervention plus the same information leaflet.

The information leaflet provided is the Family Planning Association designed leaflet titled "Planning a Pregnancy".

We also aim to assess whether the Call to Action agenda of the increased workforce of Health Visitors enable teams to provide preconception care to women attending their service.

## Outline of the project phases

### **Phase One: Set up, permissions, translation and PPI. January 2014-August 2014**

The study research team was assembled and the study protocol was refined. We went through a highly rigorous governance process to obtain the license agreement for Smarter Pregnancy from Erasmus. As the Smarter Pregnancy tool was originally developed in Dutch, we then undertook full translation of the programme, which consisted of over 60,000 words, including all coding of questions, recipes and generated email & SMS outputs.

Once Smarter Pregnancy was translated into English, we undertook testing of the tool and piloting of the programme to ensure all translations were appropriate. We then implemented suggested edits

and improvements into the programme. Our study nutritionist (Dr K Hart) then reviewed the recipes that were originally targeted to the Dutch population and applied changes to ensure they were applicable to our target population.

In addition to the scheduled programme, we also added additional surveys at baseline, 3 months and 6 months follow up periods to collect socio-demographic data and monitor impact of the m-health tool.

We also carried out PPI (Patient and Public Involvement) in Health centres and Children's centres where Health Visitors were based. We spoke to women about their views on the study protocol. This informed the feasibility of the study methods. All study information was reviewed by parent forum groups. This included the information leaflet and consent forms. This group were presented with the original protocol which described randomising women to Smarter Pregnancy or to an existing leaflet on planning a pregnancy (produced by the fpa). All women stated that if they entered the study they would want access to Smarter Pregnancy. This informed our study design so that we then generated two versions of Smarter Pregnancy – the full version and a lighter or reduced version.

Those randomised to be in the experimental arm of the study are contacted to complete the full screening every 6 weeks along with regular tailored coaching and receive 3 recipes a week. Those in the control arm are contacted every 12 weeks and received 1 recipe a week with less coaching and advice in comparison. (Details on what each group specifically received, is described in Methods).

Study governance such as obtaining ethical approval and site specific permissions were sought in this phase.

#### **Phase Two: Set up of pilot sites and training. August 2014- October 2014**

Initially we had identified two pilot sites, Bart's Health NHS Trust and Homerton University Hospital NHS Foundation Trust. North East London Foundation Trust joined the study after the first two sites had begun recruiting. A Health Visitor Lead was identified from each of the Trusts.

We then undertook training of the Health Visiting teams to introduce the study and overview of Good Clinical Practise with respect to recruiting and consenting study participants.

Each Health Visiting team was given an electronic tablet on which to introduce the study and register participants to Smarter Pregnancy.

#### **Phase Three: recruitment. October 2014-June 2015**

The Tower Hamlets teams from Bart's Health began their recruitment in October 2014. Hackney Health Visiting teams from Homerton began in November 2014. Finally, Barking & Dagenham teams

from North East London Foundation Trust started recruiting in February 2015. We had planned for a 6 month recruitment period to recruit a total of 300 women, however as recruitment initially was slower than anticipated this period was been extended to 9 months. This was completed in June 2015. All pilot sites had their project funds increased to accommodate this increase in time spent on the project.

#### **Phase Four: follow up and qualitative research. July 2015–December 2015**

Once recruited into the study, there is a 6 month follow up period, where the participant is prompted to input their personal diet, nutrition and lifestyle behaviour information to Smarter Pregnancy. Their answers and scores are collated over this period of time.

For the qualitative component of the study, a subsample from each pilot site who have already consent to be interviewed, were asked about their views and opinions of the Smarter Pregnancy tool, the study overall, health visiting and their views on preconception care.

The feasibility of this study will also be explored through in-depth interviews with Health Visitors and their teams.

#### **Phase Five: Analysis and write up. September 2015-March 2016**

Quantitative data analysis was undertaken to primarily to assess recruitment and follow up rates. Secondary analysis will examine whether there has been significant change in risk scores, over time, and between the two study arms. We anticipate the full 6 month follow up period to be complete by the end of December 2015.

A full qualitative analysis will also be undertaken of participant and Health Visitor experiences. We present preliminary findings below.

## **Study Methods**

When women were routinely invited to attend a developmental review – at 8-12 months and 2-2.5 years after child birth - they were sent the information leaflet to introduce the Start at the Beginning study. Upon arriving at their review appointments, they were approached by Health Visitors or members of their teams to ask if they were intending to or had any plans to have another baby within the following 12 months and if they would be interested in entering the research study.

Upon further interest raised from the women that are under the care of Health Visitors and the initial reduced recruitments rates, recruitment was encouraged from any and all contacts women may have with the Health Visiting teams.

Information of the study protocol was explained to the interested participant in order to obtain full informed consent. Consent is required to take part in the study; however there are opt-out options to certain activities e.g. taking part in an in-depth interview and future contact that did not affect their participation in the study.

Once consented, the participant registers to Smarter Pregnancy online using the electronic tablet and follows the prompted emails to activate their personal coaching programme. Randomisation occurred once the participant activated their registered account from their personal email to complete the baseline survey.

Those randomly allocated to the experimental group would receive the “Full” version of Smarter Pregnancy; this includes receiving screening questions on all risk factors every 6 weeks. At these time points the users receive tailored feedback on all risk factors and behaviours. They also see diagrammatic images to show their total score, lifestyle and diet risk scores on a Good-Bad scale.

Each week in between the full screening, they would receive questions based on any risk factors they may have highlighted in the screening for tailored coaching, for example if they have answered that they smoke or do not eat the recommended amount of a food group they would receive questions and prompts on these aspects.. This group would also receive up to 3 recipes per week and tips via SMS.

Those randomly allocated to the control group received “Light” version of Smarter Pregnancy. This consists of receiving the full screening questions every 12 weeks. They only receive questions regarding their pregnancy status at weeks 6 and 18. They receive generic feedback and advice, not tailored. They only see their position on the Good- slide scale for their overall ‘Total Score’, not on each diet and lifestyle behaviour. They also receive one recipe per week and no SMS coaching.

Each participant is sent one further screening at 36 weeks, 10 weeks after their last screening to assess whether behaviour change was maintained.

Inclusion criteria: women aged 18-45 attending a visit with the Health Visiting teams; planning another pregnancy in the next 12 months; no specific strict diet requirements; access to the internet and have an email address; working understanding of the English language, including reading, willing to be randomised to either of the study groups and follow the study for 6months.

Exclusion criteria: Not planning a pregnancy in the next 12 months; Pregnant women; below 18 or above 45 years of age; strict diet requirements such as vegans and no internet access or email address.

## Governance approvals

Ethics approval was obtained from NRES Committee North West- Liverpool Central.

REC Ref: 14/NW/316

## Results

### Recruitment

Recruitment occurred from October 2014 to June 2015. Recruitment rates can be assessed through the recruitment tick lists, and through completed consent forms.

The tick lists were not always accurately completed by the Health Visiting team members at every contact; however we present the data that was collected from the completed forms. They indicated that 1248 women were approached, of whom 50% (n=628) indicated they were not planning another pregnancy within the next 12 months. Of the remaining 620 women who were seemingly eligible to enter the trial, 135 (22%) were recruited into the study.

Refusal reasons were recorded through the tick list. The most common named reason for refusal was "Language barrier", followed by "Not having time." Here are some of the other named reasons.

Reasons for refusal	369
No Reason	133 (36.0%)
Language	64 (17.3%)
No Time	55 (14.9%)
No Internet Access	46 (12.5%)
Not interested	32 (8.7%)
Strict Diet	16 (4.3%)
Other	21 (6.8%)

Overall, there is large under reporting of the number of women approached as we can see from our database and the actual number of women consented was 310 women across all three sites.

### Consent Incident

There was an incident where six consent forms were incorrectly completed. It was found that 3 Health Visitors had signed the consent forms "per procuracionem" (p.p.) on behalf of the clients, with their knowledge. This matter was flagged and reported immediately. The pilot site Health Visitor leads and managers were informed. The Health Visitors in question were informed and arranged to undergo Good Clinical Practise Training once again. The issue was also reported to the study sponsor, (UCL) who are monitored the research team's actions; the research team investigated



all consent forms and recruitment practise at all pilot sites. Actions included ensuring all recruiting members of staff have valid GCP certificates and training of any new staff that join the Health Visiting service.

### Randomisation Incident

It was brought to our attention when the third pilot site, Barking & Dagenham began recruitment there was an error in the programming of the Smarter Pregnancy randomisation. Users were not randomised to either group and were following the default programme, this was equivalent to the experimental group. Upon detection this was corrected immediately leaving 34 women with no randomisation. For analysis purpose we have labelled this group “experimental 2”.

### Baseline data collection

Baseline data analysis indicates that 310 women consented and registered to take part in the study, from these, 239 women activated their programmes and were randomised to either study arm. 172 women completed the baseline survey.

As the follow up period is still in progress, (due to complete in December 2015) it has been challenging to be able to draw firm conclusions therefore we present baseline data.

Table 1 below shows baseline data by experimental 1, experimental 2 and the control group. As expected, smoking was very uncommon. However, nutritional risk scores (VRS) were similar in both groups.



**Table 1: Baseline characteristics of participants by randomisation arm**

Groups		Experimental1 N=119	Experimental2 N=34	Control N=86
Variable				
<b>Socio-demographic factors</b>				
Age, years	Median [IQR]	33 [39;38]	31 [27;35]	34 [28;36]
BMI, n=169 (79/27/63)	Median [IQR]	24.8 [22.2;29.4]	28.6[26.0;33.1]	24 [21.5;27.3]
Marital Status, n=77	Married/ Cohabiting	30	6	32
	Other	4	0	5
Ethnic origin, n=77	White	15	2	17
	Asian	7	0	9
	Black	9	4	10
	Other	3	0	0
Place of birth, n=77	Not UK	24	3	22
	UK	10	3	15
English first language, n=77	No	17	2	14
	Yes	17	4	23
Education, n=77	First degree	9	2	15
	Higher degree	13	2	8
	Other	12	2	14
Currently working, n=77	Working full time	8	2	10
	Working part time	9	1	6
	Maternity leave/looking after family/other	17	3	21
<b>Reproductive health &amp; health and diet factors</b>				
Parity (all live births), n=77	No children	14	1	6
	Yes children	20	5	30
Miscarriage in past year, n=77	No	27	5	25
	Yes	7	1	11
Are you pregnant?	Yes	1	1	2
Planning to get pregnant	No	18	3	17
	Yes	88	26	62
Do you smoke?	No	71	27	53
	Yes	3	0	3
Fruit portions per day, n=169	Mean [range]	2.3[0;7.1]	2.2 [0.2;8.7]	2.3[0.2;6.9]
Vegetable, grams per day, n=169	Mean [range]	190 [0-464]	153 [0-393]	195 [0;500]
Baseline <sup>1</sup> VRS, n=169	Median [IQR]	4[3,6]	6[3,9]	4.5[3,6]
Baseline <sup>2</sup> LRS, n=169	Median [IQR]	0[0,1]	0[0,0]	0[0,1]
Folate score, n=169	0 (no)	36	9	17
	3 (yes)	40	16	41

<sup>1</sup> **Nutrition Risk Score (VRS)** is composed of the three items - fruit, vegetables and folic acid. VRS ranges from 0-9 per participant.

<sup>2</sup> **Lifestyle Risk Score (LRS)** is composed of the of the two lifestyle habits (smoking, alcohol). LRS ranges from 0-3 3 per participant.

### Follow up data collection

Follow-up data collection online is still in progress. There is currently insignificant data at the 3 month follow up stage to ascertain significant comparison of results.

## Qualitative Research

15 women were interviewed across the pilot sites. 6 users from Tower Hamlets, 4 users from Hackney and 5 users from Barking and Dagenham. We started with those that had been in the study the longest in order to attain a comprehensive accurate account of their experiences. Users were approached to take part in the interview if they had consented to be contacted. A mutually convenient date and time was agreed and the interviews took place in the health centres. An open ended, semi structured topic guide was used (Appendix I) in these in-depth interviews, all interviews were audio recorded with consent and transcribed verbatim.

As we also wanted to assess the impact of the Health visitor implementation plan 2011 to 2015, which aimed to increase the workforce by 2015, the primary aim for the Health Visitor was to bring focus to preconception care and healthy eating with their clients. This would assist Health Visitors to focus on the Department of Health Early Years High Impact Area 4 (as mentioned above). It was therefore vital to receive their feedback to understand their experiences, to assess whether they can deliver adequate preconception care and advice.

All Health Visiting project leads and their site principal investigators were interviewed regarding their feedback and experience in the study.

All those interviewed were given a £20 shopping voucher to thank them for their time.

### Participants Interview Findings

#### Reasons for Participation

All users shared their reasons for taking part in the study, which can be seen to follow 2 main themes. The dominant theme was to improve health in preparation for pregnancy. There was an understanding in this group of the women, that being healthy before pregnancy was beneficial for the baby, this was felt strongly especially if these women had had difficulty in getting pregnant in the past.

"I just thought it would be good to just do a questionnaire to find out if I'm healthy or you know, if I am where I'm meant to be and I'm following everything that I should be" Interview 1

“You know, because sometimes, because I’m a very bad eater myself. I’m anaemic and because of my previous experience because I had also issues with being anaemic, so then, I said, “Look, I think, sometimes, you need something to encourage you, something to remind you.” Because you know, when an email is sent, its like, “Oh, I haven’t done this, I haven’t done that.” Because I remember before, you know, you get pregnant because the health visitor says, “Have you taken your folic acid? Have you done this?” So, I find it quite helpful because I had completely forgotten about that. So I had to buy that, I had to eat this because it encourages healthy eating. So, in a way, it’s actually good. It’s a reminder because sometimes, you may think you’ve had your five a day, you might think you’re eating healthy but you find that with the study, you know, it actually gives you in detail of, you know, what is healthy and all the stuff. So that’s good.” Interview 2

“it’s very good concerning your health. It help you to know the right fruit or right food to eat, when you want to get pregnant, get...help you to get ready to get pregnant, folic acid and all. That’s it just try it and see how it goes. its okay, it’s good.” Interview 9

The second theme was that these women were already actively planning another pregnancy, they were happy to receive further advice, information and were pleased to help for research purposes to assist women in the future.

“I thought okay it sounds really interesting. I don’t mind getting information coz I know at the time I was planning to have a baby.” Interview 1

“You know, I’m always happy to help. Anything to sort of help ladies, help us understand people getting pregnant. I mean, I’ve got friends, you know, who have tried for years and years and years and, you know, still never caught. And I think it’s great that you can be part of a study, you know, that’s not actually asking you to really do anything more than what you’re doing for yourself anyway. So, yeah, I’m -- it’s not like I work or anything, so I can take these times out to do a bit of extra things like this anyway. So it’s not a problem for me.” Interview 15

“I think the problem is if people don’t know, they go to Google. And you go to Google, and you get some chat on Mumsnet. And it’s a load of women feeding other women garbage. So, when I was pregnant, I was like keep off Google. Because I’ve got this symptom, what does it mean? You know. It’s like your baby’s dying. It’s all these people freaking out. And I’m think in the whole thing there’s so much false information out there. I think where do people get that from? But if you don’t know that, you go, “This is what it means,” and actually...So stuff like this just keeping people on the straight and narrow is just quite helpful. And that’s basically why I signed up to do it. Yeah.” Interview 7

### Smarter Pregnancy

Talking about the Smarter Pregnancy programme itself had mixed responses. Out of the 15 women interviewed, 4 women did not use or stopped using Smarter Pregnancy prior to completing the full programme follow up period.

1 woman changed her pregnancy intentions due to personal reasons. She used the application for a few weeks and enjoyed it. She tried a few of the recommended recipes but then stopped engaging. 2 women did not read the information leaflet thoroughly and therefore did not start the online intervention. Once the intervention was explained to them in the interview they expressed great interest and desire to have wanted to completely take part in the study. Only one user had difficulty in completing the survey questions and therefore discontinued their participation prematurely. This user liked using the programme and was quite unhappy to have not been able to finish it.

Smarter Pregnancy focuses on some lifestyle behaviours such as exercise, alcohol intake and smoking. Through the interviews, no users indicated they were smokers. Only three women stated they drink alcohol and that at low levels and not regularly.

With regards to exercise, users stated the programme was successful in motivating an increase in exercise, albeit not always translated in their actual behaviours.

"I do because I never used to exercise before -- I do exercise, but not what I do these days, before I just walked around and stuff and now I do more exercise." Interview 12

"it definitely wanted me to exercise more, I know that is one thing I always say I'm going to do, don't always do it. Erm that's one thing definitely, that I would like to improve on." Interview 1

A theme emerged from the interviews that Smarter Pregnancy had motivated, encouraged and produced a perceived behaviour change of eating more fruit and vegetables through the study period. Once we are able to analyse the follow up data, we hope to show this in the quantitative statistics. More focus and attention was given to eating fruit, in one case a couple used to eat very little fruit, however upon motivation from Smarter Pregnancy fruit was introduced in to the home and together they increased their intake.

"Yeah, he [partner] eats. Not that much fruit, but I give him enough fruit at night. I give him...since [the programme] then I start to give him enough fruit, fresh fruit or juice fruit. I make juice at home. And if I can't make that juice, I give him fresh fruit, and for my daughter. Yeah, the whole family eats it well that programme, yeah." Interview 8

"Rather I would remember, this app and I'll say fruits and vegetable. And since then, I always have fruits and vegetable in my house because of this app. But it wasn't so before" Interview 4

“Yeah, because of the App because I realise I've been eating the wrong food for so long, so I've just, I've changed the way I eat some of the -- but most of the food now, yeah. And I've now tried to be eating more fruits than before, yeah.” Interview 12

“So, when this actually came along, it actually really...truly, it encouraged me in terms of eating healthy because you know, exercise and eating healthy helps you because you change your lifestyle completely.” Interview 2

### Recipes

A coaching technique applied by the programme was to periodically send simple recipes to users to influence healthier meals and snacks. There was a reflection of an improvement of the family diet as a result of the intervention as women stated they had tried some of the recommended recipes for the family meals.

“I remember one email, said something about instead of having chips or something, it was...at the bottom it's something like instead of chips, have a baked potato. I've done that a few times. I'm sure that was Smarter Pregnancy. Or maybe it was think of other options, it was just suggested baked potato. And I thought, “Oh, I was going to do chips...But I'll do...” because I make home-made chips. They are healthier anyway. But I thought, “Yeah, I'll have a baked potato, will be healthier still.” And it's still the same ingredient, isn't it. So, I've done that a few times, and my husband really likes it.” Interview 7

“Erm the recipes were interesting and they were quite simple which I like actually. I hate cooking... It is a reminder to eat well and look after yourself, especially when you're pregnant because that is a really tough time to do that when all you want to eat is toast...” Interview 3

More than 50% of the women interviewed really enjoyed receiving and cooked the recipes. Common comments were that they were a little bland. More cultural dishes were suggested to be preferred, but users understood why these were not included.

“One thing ... I've noticed with most recipes, I'm sure it's been catered to everybody's needs but it did look a little bit bland, we like a bit of colour and spice in our food. So you have to be a bit creative and majority of it, it didn't include cultural dishes, so I think that would be nice to include maybe like a rice and curry, but in a healthy version.” Interview 1

“I think they were easy to follow because sometimes, you try things.... But I think the only challenging thing with pregnancy, the recipe made with it but sometimes, you may not really like exactly what is there, what is on the particular recipe. Because I know there's a time...early stages when I had actually sort of completely gone off my...you know, part of the greens, I didn't like them at all.” Interview 2

"I love some part of it like tomatoes soup and the one that will tell you how to do it. I love them. Yeah, it's very fine... There was a few I loved that I could recommend." Interview 4

One comment that was quite strongly felt by Interview 5, was that the format and layout of the recipes sent needed improvement. The absence of images and step by step instructions in lines reduced the appreciation of those sent.

"The recipes though, they could've laid it out a bit more.... I found it...I have a picture of this meal that you're going to prepare. You know that really helps like, visualisation or something like, "Oh actually that really looks nice." And the way the layout is it is too much blurb at the bottom. You've got your ingredients but then they need to lay it out like, step one, two, three, maybe.

It's just the recipes. That really annoyed me.

It's just like it should just be a bit more clearer, presented quite nicely. It's a bit bland and just copy and it doesn't really encourage me to...you go back it, you see what I mean? Right. People are visual...we're visual people, right? So if you see something, you think, "Oh, that's really nice." So I think you need pictures in there just to make it nicer and just lay out a bit like steps. Maybe have steps, that'll really helps. One, two, three, four, five, six. So it's not just bunched up text. So just to tidy it up." Interview 5

Only 4 users expressed ambivalence or dislike to the recipes. One user disliked receiving the recipes as they felt there was no explanation to highlight the benefits of eating the specific ingredients recommended. This was discussed to have been an additional coaching and motivation tool for users to increase the likelihood that they would have cooked and eaten the recommended recipes.

"I suppose the thing is, receiving the recipe once a week is like great, thanks very much. What would be more useful to me is to receive the thinking behind it. Try adding X, Y and Z to your diet because it's got, because it's high in whatever minerals or whatever it is that you need" Interview 13

"I received links to the recipes, but actually...well I'm a vegetarian for a start, so some of them weren't relevant, but also my partner an amazing cook so I didn't feel the need to look up any more." Interview 14

### Smarter Pregnancy for Men

Within the Smarter Pregnancy programme there is a version designed to be used by expectant fathers based on scientific evidence that the preconception behaviours of men can also affect healthy conceptions, pregnancy and outcomes. We enquired with women whether they believed their partners would be interested in taking part in the programme had it been offered to them. Response was generally that men would not be interested in changing behaviours or investing in preconception care.

“Oh god, no I doubt it, I don’t think so. [laughs] No its very difficult with men, I’ve been trying to get my husband to stop smoking for so many years now but in the end I gave up. I thought when you’re ready, you just do it. But I don’t think that this is something he would be interested in.” Interview 1

“My husband wouldn’t be massively interested and he wouldn’t care either way. But it’s not something he’d do.” Interview 3

“Absolutely not. He doesn't even know I'm doing it and he wouldn't even care if I was. He would be no good. I hate to say that. He's so crazy busy that the down time he's got, he doesn't...like he'd like us to have another child, and he will – without being obvious – he'll play his part in that.

I think men generally think that having a baby is like putting in a slow Amazon order, don't they? They place the order and nine months later, their package arrives. And kind of left to us a little bit to figure out. But I did say to him things like we're not having any prawns or mussels in the house, whilst I'm pregnant because it's not fair. He was good about that.” Interview 7

### **Smarter Pregnancy Feedback**

In the programme, once a user inputs their dietary intake and their lifestyle behaviours, their ‘risk scores’ are calculated and tailored advice on a feedback page which is visible to the user is generated. For the experimental group this page will show the user where they lie on a Good-Bad slider scale for each food group and lifestyle behaviour, for the control group they will only see general advice on each food group and behaviour and an overall risk score depiction on a slider scale rather than for each risk factor.

All users except one were positive towards receiving feedback on their data and behaviours. It was seen as essential to see how they were doing. The slider scale illustration was greatly appreciated.

“no not really. I wouldn’t really... I’m not really a graph kind of person so I wouldn’t really be looking at the graph, I don’t think so.” Interview 1

“Yeah. It was good. Because the advice underneath will tell you if you keep on...that you're doing well. Keep it up. Yeah. It's to improve my...Encouragement.” Interview 4

“So that was good. I could see a progress. Like I said before I started I wasn’t eating as much fruit and veg. And obviously I could see my progress overtime which was good. So that encourages you, I guess even more. And any data is always good to see anyway. So it’s just to assess yourself, right? So I find that useful as well. That was quite good.” Interview 5

“I think it's more encouraging because that makes you feel you want to do to more, yeah. That makes you feel you should change what you're doing wrong and -- yeah, I think that is good, yeah because that’s what I saw that makes me change eating more fruit and vegetables because I'm



thinking I thought was I was doing was good until I, you know, fill in the -- this scale thing and I find out I'm really not in the right way; so I think it's good, yeah." Interview 12

### Smarter Pregnancy Improvements

An essential element of the pilot study is to assess the intervention efficacy by the end user. We asked our sample if they could suggest any improvements or changed they would have liked to see in Smarter Pregnancy. We have mentioned some of these in previous discussions, such as the improvement in recipe layout, which was deemed vital in order to receive engagement.

As mentioned there was a feeling that although the messages of eating healthier and increase the fruit, vegetables and vitamins in the diet, further explanations should be shared to highlight the importance of why and how precisely this can improve health and impact conceptions and pregnancy health. This was thought to be more emotive than tips and advice to improve diet alone.

There were a few comments on the grammar and tone of messages sent, particularly by SMS. It would be beneficial to check all messages content and coding to ensure the correct messages are received by the correct users. Two users commented that their pregnancy status was mistaken in the message content.

"And some of the messages have been worded in quite a -- yeah, not a very empathetic way. I remember there was one about miscarriage, but the tone of it was a bit, oh, okay, a bit sudden. Because it's not like reading it on the internet and that's more passive, this is something that's actually coming in to your phone or your email box. So I think it has that sort of greater impact and it's more personal. So thinking about how it might be received. I mean as I was I wasn't upset by it but I could see others might be." Interview 14

Some users expressed slight difficulties in understanding some questions asked. The main issue was the units, the users expressed they may not measure their intake in terms of tablespoons and an option of units would be beneficial. This was also the case when asking for their height and weight. As all questions are mandatory and you cannot progress unless each question is answered, for this purpose options should be offered.

The main reported issue with regards to registration was the setting of the password. It was confusing for the users to set the password of required length with the stipulations of a capital letter a number and a special character. The only other issue raised was the format when inputting registration details, in some headings specific capital or non-capital letters were required. It was requested more direction or outlines of what is required should be around each heading.



### Preconception Information Views

The literature already has great breadth to show the requirement and importance of sharing preconception advice on health and behaviours this view was also shared by our participants.

“Yeah, exactly. Right before. You change your lifestyle before.... As soon as you think, “Okay, you know what? I do want to have a child in a year or something,” you change then at that point. As soon as you’ve thought about it, the bubble pops, you change. You don’t wait, you change then.”

Interview 5

“Anything that helps mums and mums to be I think you’ll find new mums and that sort of stuff and bring all the information there and if it makes one extra person take their folic acid and have a healthy baby then that’s amazing!” Interview 3

“Well you need to tell them that: This is what you need to do to... Because definitely, if you take the folic acid, eat more fruits, you know, healthy food, anyway, I think it will help go a long way. Because most people think, oh, I want to get pregnant; most people don’t even know where to go to get the help when it comes to pregnancy.” Interview 9

There was also a sense that the women felt there should be a network or a place where they can talk to one another, as it can be a lonely place.

“But I think i can say because it sometimes can be quite lonely. Coz you’re not talking to your Dr yet and you can’t tell your family about it, it’s nice to have... and you mentioned the app and that you can do it on your phone that its anonymous and not on your work computer that great.” Interview 3

“My personal opinion -- people that are trying, who can't fall pregnant as easy, should talk to each other because that's one thing I found that no one every spoke. When you went to the hospital and you were all in that waiting room you all knew what you were there for, but everyone didn't talk to each other.” Interview 10

“If it’s through having a like small gathering, you know, through tell people to come to the social centre, sit together where you discuss it. Because most people don’t even know, you know? Yeah, put it through leaflets like this, send it out, distribute it to people who’s going here and there. They might...some people have interest to read it” Interview 9

### Identifying Target Population

The difficulty often faced by researchers and health care providers is to ascertain a sample or to identify the population that would benefit from such support. There is a sense of great secrecy with regards to pregnancy planning, where women are reluctant to reveal their intentions or even once they conceive until they are past their 12 weeks scan, which you could say is a crucial time in pregnancy health

We put this to our users. It was unanimously agreed that finding women for their consecutive pregnancies is considerably easier than finding first time mums. It was also accepted that once you have had a child, you seem to already have the crucial vital information on preparing for pregnancy. It was also revealed that once you have a child you seldom have time or attention for major lifestyle changes to prepare for the next pregnancy.

Examples of places and ways to promote preconception health information were discussed and a general list can be made. The most common place mentioned was the GP surgeries, followed by online websites, such as NHS and MumsNet etc. Advertising in Magazines, on billboards, bus stops and on trains was popular to find first time mums. This way it is in view for the general public so those that may not be regularly seeing health care professionals or actively searching for preconception care and support are exposed to the advice that is available. Other examples were followed by advertising in Gym's, Supermarkets, Pharmacies and on Social Media.

### Participant Views on Health Visitors

All women interviewed had no qualms to be approached and asked regarding their current and future pregnancy intentions in the Health Visiting setting. As it was asked by whom they deemed as a health professional and in order to offer support.

"I didn't mind. There were a lot of locations I wouldn't mind. And in there, and the lady was lovely. And it wasn't awkward for her to ask. And erm no I think its fine to ask. I didn't have my partner with me but he wouldn't have cared. No I didn't mind at all. I hadn't thought about that actually, ye some people might be a bit fussy but no. not me!" Interview 3

"It's fine. Yeah, it's fine. No problem at all. I was on the topic, so it wasn't like they forced it upon me. They just asked that, "Would you be interested?" So yeah. It was approachable and they were friendly, it was nice." Interview 5

"Yeah, I think, absolutely. Because I know, for the midwives, they only see them once they get pregnant. So, I think the best place would be the health visitor. But...and I think maybe it could be advertised more because I'm just thinking of what about those parents that don't have children that are planning to get pregnant? That is very challenging so I'm not sure that would be advertised. Because if it's a second time mother, yes, it's okay, you can get your clients that way. But if it's a first time mother, where do they get such information? So then, I think it's something that...I'm not sure how it's going to be advertised." Interview 2

"Yeah, I mean, I think that initial one -- and it was a great time to do it as well at the assessment if you see what I mean because I was already there, I'd already got the appointment, you know, it was quite a good time for them to sort of get me if you see what I mean, to have a chat with me." Interview 15

### Participant Views on Further Study

Further research study plans for Smarter Pregnancy was explained for their feedback and interest. This would entail a randomised control trial with a longer follow up period. Women who are planning a pregnancy would be randomised to use Smarter Pregnancy through their preconception period to pregnancy and birth to assess the impact of the app on birth outcomes along with Health Professional support in the form of face to face interactions of phone calls. Whilst the control group would be given the FPA planning a pregnancy leaflet and no access to Smarter Pregnancy. These are the user's response to the protocol.

"I definitely think more could be done. Yes definitely. I think erm... face to face would be helpful with a health care professional would be a good idea, coz that would be more motivating for a woman to carry on, definitely, maybe group sessions or you could do like er a little... little seminar or where you can get other women together, so women can meet other women and discuss how they are doing in the programme and compare results and get tips and advice that would be quite wonderful really. But I can see more people going for meeting a health professional and talking about it, I've seen a lot of women doing that, I think that would be a good idea, definitely" Interview 1

"Sure. I think you'd have to provide an incentive because, yeah, that would be quite a -- given that when you're pregnant and giving birth, there's a lot going on. So to keep women engaged, there would have to be something quite attractive about that. Whether that be a financial or some other sort of support they'd get. And, yeah, I think people entering a study realise they might be in the control group, or whatever. So I don't think that would be an issue." Interview 14

"And I think, you know, people want the information. They definitely want the information, but I would say that if there was a benefit for them to do it without the app, I think you would have to probably give them something to do it. Whereas the ones that you were giving the information to for the study, I think they would be more than happy to just do it, to be part of it. Whereas the ones that you weren't giving the information too, they would probably want some – I'm not saying that a financial sort of benefit, but they would probably want something in return, if you see what I mean, for taking part without the information." Interview 15

"well I think that's great. Anything that helps mums and mums to be I think you'll find new mums and that sort of stuff and bring all the information there and if it makes one extra person take their folic acid and have a healthy baby then that's amazing!" Interview 3

"I think they might be involved before they get pregnant, after the baby. I don't think you'll get much response personally. Because I think you just don't have the time.

Women struggle, you know? Our life has changed. It's really fast-paced. For example, I've only got one, I planned to have a second one. After the second one I'm going to be really busy like, with work, two children, managing the house. It's not easy, you know? So I personally think before getting pregnant, fine. Maybe if you've had one child then you've got a balance so that'll probably still continue. But once you have more than two, I don't know. I don't think you're going to get a good response personally. I don't think it's going to happen" Interview 5

## Health Visitors Interview Findings

Each site had a lead Health Visitor; in the case of Barking & Dagenham two Health Visitors shared this role, in Tower Hamlets, there were also two additional support workers that had protected time to spend on this project. When the project was introduced these Health Visitors expressed great interest to being involved with research and nutrition hence applied for the role to lead the projects in their boroughs.

### Participation

However when the study was introduced to the wider teams to begin recruiting their response was inconsistent. Many of the Health Visitors and student Health Visitors recognised that this was an opportunity to bring preconception back on to their agenda, as they admitted it does get forgotten amongst all their other targets. Their concern however was their lack of capacity to embrace the project, which then largely fell onto the leads. In one site the team were enthused and on board however time and setup guidelines hindered participation of full teams, through the need for recruiters to have a valid GCP (Good Clinical Practise) certificate. This course was time consuming and Health Visitors did not make the time to complete it.

"The only concerns we had was we had to do everything in the sense that the other health visitors, they did not have the time. They didn't have the time to you know because we were supposed to invite this client over, during maybe eight months review to one month...one year review and maybe we try to review two and a half year checks and all that." HV5

"Our own roles and how that fit into our whole role -- our own role in terms of health commission which is a public health role promotion of health visitors. We had a few that became quite interested, but sometimes the work pressure there would not allow them time to go into what they said and didn't give them enough time to do much recruitment or also publicising the project as well." HV3

"And they felt it was just yet another piece of work they've been asked to do. Not really asked, been told to do and that they didn't have a choice. That was, I think that was the main thing. And that

really lost...it sort of lost ground because you've already had resistance, people saying, "Why should I do this? Nobody told me. Nobody asked me what I think of it." I don't really know how much difference it would have made but I think it's just people like to be told what's going on. And I think we were very short-staffed at the time, beginning of the study." HV1

### Setup

With the case of Tower Hamlets, their increased workforce as a result from the Call to Action Agenda was yet to fully be implemented. At the time of implementation their teams felt they were already working above capacity and could not commit to the extra tasks of introducing and recruiting to the study. There was also a change in leadership and management structure, which we believe impacted the momentum and progress of the study.

With Hackney there is a similar story, they were also subject to high turnover of Health visitors and changes in management structure however the impact was less severe. The Call to Action did result in an increased workforce; however this was only felt towards the end of the project timeline and was not present throughout.

As there was a delay for Barking & Dagenham to begin recruiting, this worked in their favour as it began after the increase in workforce had occurred. This pilot site did not experience concerns regarding capacity that the previous two sites felt.

Health Visitors were initially engaged in Hackney but there was a delay from the introduction and training of the study to the implementation due to setup protocols, which caused a reduction in interest from the teams. There was also a strong sense that the project was not their own and, similar to Tower Hamlets, was seen additional work on their already full case load. Those motivated appreciated how this project could be incorporated into their role and how it was a core part of their work.

In Barking and Dagenham only the two Health Visitor leads were qualified to consent and recruit participants as they underwent GCP training. It was felt that the rest of the team did not have the time to undergo the online training that their R&D department required. They trained all staff on the project and introduced the study to their clients, if any presented interest, with their consent their details were passed on to the leads who would undertake full informed consent and registration of the user.

"I found, initially, I found that the study was not from sort of management level. Health visitors were not consulted. I think that was the main thing where it was not really well publicised so therefore, it was not well-received. On my...when I found out about it, it was a locality meeting. It was not a health visiting forums. It wasn't a wide audience. It could have been a wide audience and

a lot of people didn't know about it until we went around, I myself and you to do the training that was...a lot of health visitors, that's the first time they had" HV1

"That would be good because they should realise that it's not just another piece of work, another piece of extra work on their main caseloads. So it's – if we own it it's a part of the thing that is integrated into the core services, you know, obesity is an issue. You know, there could be complications, the issues around obesity. And how we can catch, you know, clients early. You know, planning pregnancy, healthy pregnancy, healthy lifestyles. Kind of translate into how the children as well as the reduction of the issues around obesity. So I believe if we took it on board and you know that it's part of what we have to do, it shouldn't be just like, coming as another extra piece of work." HV3

One of the main recommendations to prevent such situations in the future is that full stakeholder participation should be sought when developing the study protocol. As the main drivers of recruitment their input and opinions on how best to execute the study could have been valuable. It is now accepted that Health Visitors themselves would have been well placed to advise on where would have been most suitable to recruit women planning their subsequent pregnancy.

Another way to enthuse the Health Visitors is to carry out more publicity around the projects, its benefits and synergy with Health Visiting practise. It was suggested that more focus is needed to inform and education Health Visitors the importance of research and evidence in practise.

"What I would suggest is the orientation of the health visitors, you know, towards change, towards research. Our own orientation is to change as well an understanding where -- what has to inform our practice and the need for us to evidence what we are doing. So that is the message I always try to put across to health visitors." HV3

"And it's actually made a difference to a lot of the health visitors because now, I think it was [HV name] and I enjoyed it so much and (Laughter) that came across to people. Everybody wants to get involved in the research now. (Laughter) Everybody who is coming to health for their professional development meetings and stuff, people want to get involved because this really opened their eyes." HV4

## Recruitment

The levels of involvement from the pilot sites varied from the Health Visitors and students from refusal to take part in the study and recruit, from understanding the importance of the project and agreeing to introduce the project if they have time. In such sites the lead suggested they only introduce the study to their users and if they seem interested to pass on their contact details for the research team to follow up, however this got little response. The management of these sites were



requested to encourage and support recruitment with all staff members, but it seems there was little effect of this, as recruitment was primarily carried out by the site leads.

Health Visiting teams were highly encouraged to bring focus to their 'public health' role as they went out into public spaces to share the project and what they were doing through market promotional stores, attending faith centres and churches and in local public parks, this increased the awareness of both Health Visiting services and the importance of preconception care.

As recruitment had begun very slowly and we had low levels of Health Visiting involvement and motivation, we introduced incentives in the form of shopping vouchers for the site that recruited the highest number of participants in each calendar month. Each pilot site principal investigators decided how to best distribute the rewards for recruitment. This had mixed reviews from each site. In Barking & Dagenham it really encouraged recruitment and the healthy sense of competition boosted their work. However in Hackney and Tower Hamlets there was a sense of the disapproval as the rewards were distributed to members of the team who contributed directly to the study the assumption was the reward was the right of the entire team even if they did not contribute.

"So when the reward came, eventually, there were so many people that got in the different teams said oh, maybe I meant they were promised £500 voucher. And I said no, it's not even -- you were not even entitled at that point. It's just that it's got to be spread around. Like I said now, we're going to do it maybe half then we're going to leave half to a later part of the study. Of course, that was the discussion of the manager, what he thought, what he feels, but I did not see that to be a kind of motivator for them to recruit. I did not see any much difference in approach, yeah." HV3

"Because when we give it, initially we did give out to the teams. But eventually, we said we're giving out individually because we found out that when we get them out individually the enthusiasm to recruit more people was there. Do you understand? Rather than, "Okay, you share this amount of vouchers for the whole team." When some people haven't even done anything. But when we say, "Oh have these vouchers for your effort and everything." Then the other people will you know. They'll say, "Oh really? I can get that." So it made it more... So it was decided that you know we're not giving to the teams anymore. We're going to give it to individuals. And that has worked." HV5

"The recruitment, initially, it didn't look like it did but once you've actually won one month, it did seem to have impact. But then, people took it the wrong way and said, well, you know, it is won by [site name] it should be shared by amongst all of [team name] including health visiting team which was difficult to explain to them if you hadn't contributed in some way why should you be rewarded. So, really it was one of the people that I had mentioned, quite a few people actually got offended when their team members got a voucher. So, "Well, we work together. What about me?" And I'm like, "Well, you didn't contribute." So, in a way, I think it did motivate the people who helped us, and...but it did have the opposite effect (Laughter) so, which is not what we were hoping for." HV1

### Training for Health Visitors

There was a sense that Health Visitors themselves may need educating on preconception health and care in order to provide a proficient service, as the impact that it can have on child health and outcomes is easily comprehensible for Health Visitors.

“The interesting thing is what we did when we were talking to the health visitors, presenting it to them; we ask them what does the term preconception mean to you? (Laughter) That was interesting. Everybody said....What is it they say about this? Folic acid. Every single person said folic acid because that's the only thing that came to mind for preconception health. So that was interesting because it's much more than folic acid isn't it?

It wouldn't be a far stretch to get people [Health Visitors] to see where we're going with this because I think they get it.” HV4

### Women want Preconception Care Advice

From the perspective of the Health Visitors they received a lot of enthusiasm from women that wanted to be involved. There was a sense of missing assistance, they didn't have any support in this period and they were ecstatic that now they did.

“Diet and lifestyle isn't necessarily...generally, when you talk about it, you're talking about the whole family but this was sort of more focused on them. So they were quite keen to know more.” HV1

“They were hungry for this sort of thing. And most of them will ask us, “Are you sure we don't have to pay for anything? ...Because they couldn't believe that you'll be offering something like this and they don't have to pay anything for it. And I think as well because the clients that we do, or maybe not because of the clients we do, I think in general, a lot of healthcare professionals have this idea that a lot of babies aren't planned. But we found that must be the case. A lot of people do plan their pregnancies.” HV4

“I don't think we spoke to anyone that just didn't want to know about the study. Everybody was really amazed that this study is being offered. And all those that didn't accept that was either because they have children or not planning... But they all said the same thing, “This is fantastic. Why didn't I get the chance to do this when I was having my baby?” So the feedback was highly positive.” HV4

“I think the most, the biggest thing for us was the, what it meant to so many of the clients because you would not believe the stories we were told you know. Like one young lady said to me, “Oh my gosh. I can't believe this. It was just this week my partner and I was saying we have to start a family and we're going to go to the GP for advice.” She was like, “I can't believe you just appeared and give me all of this.” And then you have others who would break down in tears and they will tell you how long they've been trying to have a child. And it's like any, although we explain you know you'd be



with these two groups. And we don't know which group you'll falling into. They still wanted to be a part of it because the chance of any sort of help would make a difference for them." HV4

### **Everyone Wants to be Involved**

Health Visitors also encountered those that were very interested in Smarter Pregnancy, but did not meet the eligibility criteria. The perception from the Health Visitors is that there were some men that also wanted to be involved.

"But even those who are not planning pregnancy will listen to everything you say and then say, "It's really interesting but I'm not planning a pregnancy. But we'll take the leaflet." And take the information and say, "Could I take an..." I had a few of them say, "Can I sign the consent form even though I'm not planning pregnancy." And say, "No, you can take the leaflet but not sign the consent form. Then, you have to be planning." HV1

"And a lot of men as well want to be involved in this.

We have, I think the recent two visits that I can remember, one of them was referred to us by another health visitor. So I'm not sure what conversation she had with the couple before (Laughter) but when I get there dad was sitting down waiting to sign up as well. (Laughter) So I had to explain to him at this time, it's only mum we needs to consent and sign. And he was offended you know. He was like, "Well it does it take two you know." (Laughter) Yeah and another guy was arguing, he said, "But I don't understand why they wouldn't get us involved because we play a vital role." So it's really an eye opener that men take these things seriously and a lot of them would want to get involved. We also had people calling us up who saw you know like our flyers.

And it's the husbands that would call. A lot of guys took the initiative, they were very proactive in getting involved in this. One of them, the husband wanted to sign the consent. And every time, I have to say, "No, no, no. We have to get mum." (Laughter) But yeah, so it was really good to know that a lot of the fathers want to be part of this process as well." HV5

Overall it is encouraging that we can see there is a need for preconception care in Health Visiting practise and it would be well received by both providers and clients. We have learnt many lessons in terms of how to get stakeholder involved, enthused and motivated to take part in preconception care delivery.

## Discussion

The data on recruitment show that the Health visiting setting is appropriate setting in which to identify women planning a pregnancy and offer the support to improve nutrition and other health behaviours before pregnancy.

In-depth interviews with users identified the need for preconception tool, overall it was well received. It was well understood that women wanted to be healthy and in good shape prior to pregnancy. They wanted to improve their lifestyle and behaviours. Without the programme, women were left to look online and sources such as friends and family for advice on preconception care.

There was a perception that Smarter Pregnancy helped to improve their fruit and vegetable intake through the tailored coaching and reminders. The feedback pages were well received and helped to improve behaviours of the user and their family through the use of the recommended recipes. Women recommended changes to Smarter Pregnancy to improve the experience.

Through interviews with women, it was perceived that men would not engage with such an intervention; however Health Visitors report that men were interested to take part and be involved in the preconception period.

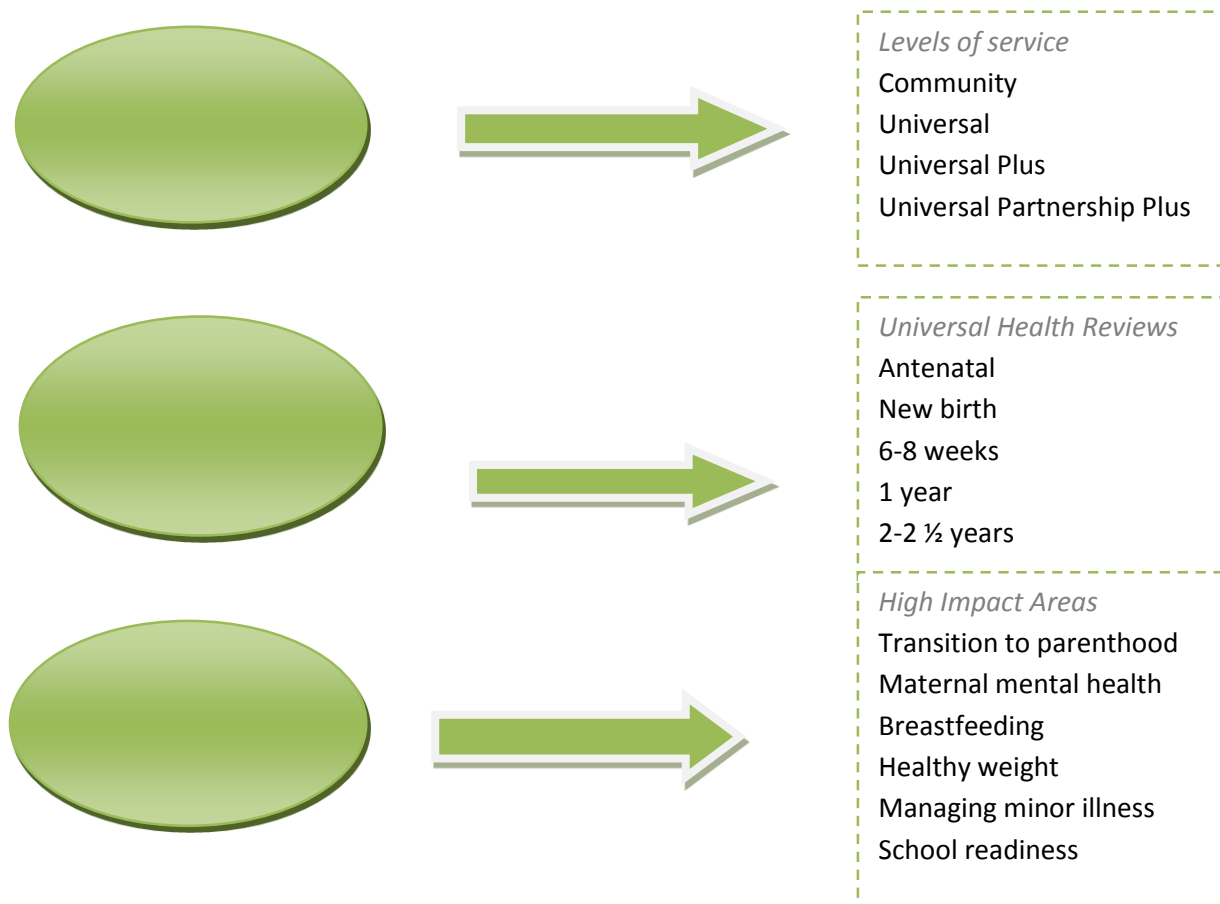
Through interviews with the Health Visitor leads and the site Leads, we have found that Health Visitors were initially reluctant to participate in the study, as they did not have the capacity to support recruitment. In sites where the increased workforce was achieved, the project did well and was well accepted by the Health Visiting teams.

There were also delays in the setup procedures that reduced the enthusiasm that was originally felt from staff members, leaving the recruitment to the few. Additional engagement with teams at the onset of the project could mitigate the negativity. Clear incentives could also be a mode of encouraging participation.

Health Visitors stated that there was a need to involve their team at an earlier stage of project development so that they can contribute and feel a part of the process. Health visitors also shared that there is a need for training in preconception health and care in order to provide advice for women planning a pregnancy. They also expressed that they were well placed to provide preconception care to their clients.

The majority of Health Visitors reflected that preconception care was important and they were well placed to cover this topic with mothers for their subsequent pregnancies. It was expressed that women under the care of Health Visitors were very keen to participate and receive support for preconception care and advice on nutrition, diet and lifestyle. They highlighted the need to target first time mothers, which they are unable to do in structured practise, but are motivated to return to practise of being out in public spaces to encourage public health in the community.

The Health Visitor Implementation Plan (Department of Health, 2011) outlines a model of progressive universal service provision offered to families by their health visiting services which they have named the **4-5-6 Model** (



**Figure 1: Components of the Department of Health's 4-5-6 model of health visiting (Dept. of Health, 2011)**

Each level of service as outlined in the model is targeted to families dependent on their particular individual needs:

- *Community:* Health visitors have a broad knowledge of the needs of the community and the resources available to them (e.g. children's centres) and work to disseminate information about them to families
- *Universal:* Every new mother and child should have access to a health visitor and receive relevant developmental checks and information

- *Universal Plus*: Families should have access to timely, expert advice from health visitors on specific issues, such as postnatal depression, when they need it.
- *Universal Partnership Plus*: Ongoing support is provided by health visitors in partnership with other relevant local services where there are complex, multiple or ongoing needs.

This research also demonstrates one aspect of how Health Visitors are able to deliver the community element of the new model by having the flexibility to be proactive and take services out into the wider community like supermarkets.

### Next Steps

We aim to complete the study follow up period and analyse the quantitative follow up data.

NIHR has advertised a commissioned call for research into implementation of preconception interventions. We are preparing to apply for further funding for a larger study to examine the effectiveness of m-health interventions based on and informed by the findings of this pilot trial.

## References

1. Group APP. All Party Parliamentary Group for Conception to Age 2 – The First 1001 Days. 2015 [cited 2015 30/09/2015]; Available from: <http://www.1001criticaldays.co.uk/~criticaldays/UserFiles/files/Building%20Great%20Britons%20Report%20%20APPG%20Conception%20to%20Age%20%20Wednesday%205th%20February%202015%282%29.pdf>.
2. NHS England. Five year forward view: Department of Health 2014.
3. England N. Health Visiting Programme. Available from: <https://www.england.nhs.uk/ourwork/qual-clin-lead/hlth-vistg-prog/>.
4. WHO. Global action plan for the prevention and control of noncommunicable disease 2013-2020 2013.
5. Stephenson J, Shawe J, Copas A, Morris S, Pandya P, Barrett G, et al. Report to the Department of Health Policy Research Programme (Project Ref 006/008). Pre-pregnancy health and care in England: exploring implementation and public health impact. 2013.
6. Barrett G, Smith G, Wellings K. Conceptualisation, development and evaluation of a measure of unplanned pregnancy. Journal of Epidemiology and Community Health. 2004;58:426-33.
7. Reynolds R, Allan K, Raja E, Bhattacharya S, McNeill G, Hannaford P, et al. Maternal obesity during pregnancy and premature mortality from cardiovascular event in adult offspring: follow-up of 1 323 275 person years. BMJ. 2013;347(f4539).
8. Robinson S, Marriott L, Poole J, Crozier S, Borland S, Lawrence W, et al. Dietary patterns in infancy: the importance of maternal and family influences on feeding practice. The British journal of nutrition. [Research Support, Non-U.S. Gov't]. 2007 Nov;98(5):1029-37.

## Appendix I

### Start at the Beginning - Topic Guide

*Thank interviewee for agreeing to interview Tell interview what interview is about:*

Thank you for taking part in our study, Start at the beginning. We are now talking to women that took part in the study, so that they can share their opinions and thoughts about the study. I have a few specific questions to ask, but feel free to share any other thoughts you may have.

*Confirm recording interview*

*Reassure confidentiality- if taking notes inform participant*

General background information

*Check information/Find out if any changes since completion of registration:*

*PROBE:*

Age	Housing/ Who lives here	Marital/partnership status	Education
	Number of children	Employment	

*Currently pregnant?*

*Would you still like to get pregnant within the next 12 months?*

*When was last baby?*

*Taking part in the study*

*Aptly, let's start at the beginning! How did you find taking part in the study?*

*Why did you decide to take part in the study? Speak to anyone about it? Own decision, joint decision? (partner/health provider)*

*How was the study introduced to you? Do you remember who by?*

*Any comments or suggestions on how you were recruited?*

*Did you feel you were given adequate information about the study aims and Smarter Pregnancy app?*

*What further information would you have liked to have?*

*What could help make the introduction clearer?*

How did you find the consenting/ registering/ activating process?

Had you sought any information on planning a pregnancy/ what sources/ what info/actions taken before enrolment to study?

Where from? Where is information currently available?

Smarter Pregnancy

*How did you find the use of the online programme app?*

- interface/screens
- completing the questions
- helpfulness
- ease of completing the questions?
- best /worst thing about app?
- would you recommend it to others? yes/no, why?
- frequency of contact? Emails/texts

Any examples where you had any difficulty in completing the questions?

-suggest any changes

Recipes:

Did you like receiving them? More or less frequent?

Did you make any, which ones? Did the family enjoy or just for self?

What would you have liked to receive?

Any suggestions on improvements to recipes?

What did you change, if anything, about your diet and lifestyle while you were waiting to fall pregnant? expand on what and what made them do this?

(if made) - Would you maintain these changes, without app support?

(if not)- probe reasons without implying guilt –could the app help to support women who would want to change their lifestyle?

Can you tell me about any of the advice you followed or found helpful? Anything/advice you didn't like?

Did you use any of the advice contact details on smoking, alcohol or other?

How did you find the feedback? Texts? Graphs and risk scores?

Would you like further support in the behavior change? Face to face? Phone calls from health professionals?

How else can we support women when they are planning a pregnancy?

*-additional lime surveys?*

*Did you receive the purple fpa leaflet? (have sample)*

Did you find the leaflet useful?

-did you follow its guidance?

-is there anything of particular use or non-use?

-would you recommend it to others?, yes/no, why?

Helping women before pregnancy

*What do you think are the best ways to help women to be able to do things in preparation for pregnancy, like take folic acid, alter diet and nutrition?*

PROBE - ideas about best ways to give information to women

- ideas about best ways to help women do pre-pregnancy actions

How did you feel being approached whilst at the Health Visitors to be asked if you were planning any more children?

Do you think being asked by the health visitor was a good place to speak to women planning a pregnancy? Where else do you think we can ask women?

Future study plans

*Introduce further study plans, ask their thoughts on it and if they would take part.*

Would you be interested in taking part in a study similar to this but that continues till pregnancy and birth? This would be to see if the app/health behavior changes can have an impact on birth outcomes, such as birth weight and delivery etc.?



-would you be interested in taking part if you were randomized to either getting the app or not getting the app? We may need to do this to really see the impact of the app

### *Closing*

Do you have any other thoughts or suggestions to share on the study?

Would you like to be informed of any reports/publications of study findings? Confirm email address.

*Thank interviewee give them their voucher*