Evaluation of the National Health Service Diabetes Prevention Programme Demonstrator Site in Salford

Report 1: Understanding the Salford IGR Care Call Service Model

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Section 1: Introduction – non-diabetic hyperglycaemia (NDH) and diabetes prevention

Non-diabetic hyperglycaemia (NDH) is a term which covers terms previously used to describe the decreased ability of the body to regulate glucose effectively, such as impaired glucose regulation (IGR), impaired glucose tolerance (IGT) and impaired fasting glucose (IFG). It accounts for conditions where blood glucose levels are above the normal range but are not high enough for a diagnosis of type 2 diabetes mellitus (T2DM). People with NDH often have no symptoms, but every year 5-10% of those with NDH will go on to develop T2DM if left untreated[1]. Around 80% of cases of T2DM could be delayed or prevented through making lifestyle changes. Once T2DM has developed the body can no longer regulate insulin effectively.

The health implications of T2DM are serious, with poor control (i.e. high blood pressure / low medication adherence) resulting in loss of vision; low mood, depression and anxiety; neuropathy (pain, altered sensation such as burning, itching and tickling, lack of sensitivity), and in severe cases, limb amputation. Further, T2DM carries with it a high-risk of developing other cardiovascular health complications[2]. T2DM is thought to cost the NHS £10 billion per year[3], around nine per cent of the total NHS budget. These figures highlight the importance of diabetes prevention as a national public health concern. The main causes of NDH are behavioural in nature, including poor diet and limited physical activity[4]. Indeed, evidence suggests that making changes to lifestyle behaviours which reduce weight, such as increasing physical activity, can decrease the risk of NDH developing into T2DM by 50%[4, 5]. However, the asymptomatic nature of NDH means that people often go undiagnosed and untreated, therefore remaining at a higher risk of developing T2DM.

To tackle this problem, Diabetes Prevention Programmes (DPPs) have been developed and implemented worldwide, including the USA[6] and Finland[7]. Such programmes aim to reduce the incidence of diabetes by targeting dietary and physical activity behaviours of those considered at risk of developing T2DM. Large randomised controlled trials (RCTs) of these programmes have demonstrated that lifestyle interventions can reduce the risk of developing diabetes by up to 58%, through a relatively modest weight loss of 5-7%[7, 8]. This illustrates the importance of weight loss, as the risk of diabetes was found to reduce by 16% for each kilogram of weight lost[7]; it also highlights the role of obesity in the rise of diabetes and supports the targeting of weight reduction to prevent cases of diabetes[4].

NHS England, Public Health England (PHE) and Diabetes UK have recently initiated a UK national diabetes prevention programme. During 2015-2016 seven demonstrator sites, including one in Salford, were commissioned to test innovative approaches to programme delivery, with the expectation that the learning from those sites would shape the UK-wide programme. *Healthier You: The NHS Diabetes Prevention Programme* (NHS DPP) will start during 2016 with a first wave of 27 areas covering 26 million people, half of the population, making up to 20,000 places available. This will roll out to the whole country by 2020 with an expected 100,000 referrals available each year after.

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NIHR CLAHRC GM was funded by NHS DPP to undertake an evaluation of the Salford demonstrator site. This is the first of three reports of that evaluation. Further reports will be written in the summer of 2016 and early 2017.

The delivery of Salford Care Call by phone to patients with NDH has been the subject of two previous evaluations. Those who received the telephone service were followed up a year later, and were found to have improvements in fasting glucose, weight and BMI[9]. The results suggest that this approach may be effective at sustaining long-term behaviour change and improved outcomes, thus reducing risk of T2DM. However, these were small observational studies. This evaluation seeks to identify the evidence base for Salford IGR Care Call.

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Section 2: Research objectives and methods

This research objective for this evaluation was to:

> *Describe the Care Call service model; present the evidence that underlies it, and look at the extent to which Salford's telephone based intervention approach aligns with the service model and evidence underpinning DPPs.*

To complete the research objective, three research questions were considered in the evaluation design:

i) How can we describe the Care Call approach, and the models, approaches or theories that have influenced its development and delivery?
ii) What evidence is there in the academic literature for those models, approaches or theories?
iii) To what extent does Salford's telephone based intervention approach align with the service model and evidence underpinning DPPs?

The following methods were used to gather evidence to answer the research questions:

1) Qualitative scoping interviews were conducted with 11 key informants, purposively selected to include those involved in the conception, formation, management, design and delivery of Salford Care Call – providing a well-rounded perspective of the service. 6 interviews were with individuals and five Care Call Health Advisors were interviewed as a group.

   We used the TIDieR[10] (Template for Intervention Description and Replication) as a framework for structuring a topic guide for the interviews and to subsequently describe Care Call based on the interview data (see appendices 1 & 2). The template has been created to ensure consistent reporting of health interventions. The purpose of the interviews was to:
   a) Describe the Care Call service
   b) Identify the evidence it is based on
   c) Identify documents for the desk research.
2) Desk research. We examined relevant documents relating to Care Call, including: reports, journal articles, presentations, scripts, staff training materials. We examined documents from the NHS DPP relating to the evidence surrounding diabetes prevention programmes.
3) Literature review. The literature review was conducted after we completed the interviews. The literature review explored what evidence there was for the Care Call approach. It covered the following themes:
   a) If the interviews identified any overall models on which Care Call is based, we:
      i. identified systematic reviews of research evidence for those models
      ii. tried to assess how closely Care Call follows the models.
   b) Evidence for any of the behaviour change techniques used by Care Call
   c) Extent to which Care Call follows the service delivery model indicated by the PHE systematic review of diabetes prevention programmes.

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Section 3: Description of Salford IGR Care Call – using TIDieR template

1. Name
Salford IGR Care Call

2. Why?
The goal of Salford IGR Care Call is to reduce the risk of diabetes in patients with a diagnosis of NDH, by use of regular telephone calls from a health advisor. The core elements of Salford IGR Care Call are:

1) Educational messages. Patients are initially given the Leicester booklet, which helps people to understand why they are potentially at high risk of getting diabetes and provides ways to lower that risk. Educational messages continue to be delivered throughout the telephone follow up.
2) Goal setting and action planning (see appendix 3). It is about negotiating what the person wants to do, not telling them.
3) Health advisors are trained in motivational interviewing by the Advancing Quality Alliance (AQuA) to help patients achieve/set new goals and form/review/maintain action plans.

3. What?

1) **Scripts**
   The phone calls are guided by a series of scripts. Each script is on a different topic, but patients can prompt a return to a previous topic. IGR Care Call uses similar scripts to Diabetes Care Call, but with a focus on diet and exercise. The scripts were all written by a diabetes dietitian or diabetes specialist nurse, based on evidence from the British Diabetic Association[11], NICE[12]. The scripts have been updated annually by the diabetes team, to ensure they are based on best evidence, and a service level agreement (SLA) is being set up to ensure that continues (last update 2014).
2) **Pathway**
   The phone calls follow a pathway (see appendix 4).
3) **Educational materials**
   All patients receive the Leicester booklet prior to the first action planning call.
4) **Patient records**
   The telephone advisor has restricted access to an electronic patient record (Salford Integrated Record - SIR), so they can see diabetes-related test results and weight measures. They collect self-reported weights from the patients and add them to the record. This access is seen as very important to the success of Care Call, because the advisor can use this information in the conversation and can see, for example, if the person is currently in hospital. Having this information conveys to the recipient that the advisor is part of the NHS and can be trusted.
5) **Written materials**
   The health advisors have a stock of information leaflets they can send out to patients. These include: Home exercises, information on the Salford Community Leisure Active Lifestyles team, Salford Heart Care Healthy Heart Clubs (only for patients who are also diagnosed with a heart condition).
6) **Information bank of resources**
   Resources that can "help people implement their action plans", for example local cookery classes, walking groups, education groups (including PLANS resources). The PLANS study[13] was delivered by CLAHRC GM, and led to the development of a website that produces a

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personalised list of local activities including exercise, diet groups, social and hobby groups which support particular health and social needs. This also includes approved resources from various organisations, such as World Cancer Fund information on portion sizes, and a Diabetes UK shopping card on sugar content. In the past a DVD was produced and acted by a Salford dietitian, and was sent to everyone to provide a visual representation of portion sizes. This is no longer used.

4. What?

Patients are referred into the SRFT Diabetes Team by primary care or community teams.

4a. Diabetes Team

1) Triage: check the necessary information has been provided (weight and BMI within one month; HbA1c result within six months of referral, to check on eligibility). If not provided, check the SIR or confirm with GP practice. The BMI and weight information is used to discuss targets for weight loss during the action planning call (APC). (NB. There is currently an additional stage of the pathway relating to recruitment to the Comparison of Active Treatments For Impaired glucose regulation (IGR): a Salford Royal NHS Foundation Trust and Hitachi Collaboration (CATFISH) trial. This is not described here as it relates to research administration rather than being part of the core service.
2) Introductory conversation and booking of the action planning call by a member of the administration team.
3) Leicester booklet sent out – this helps patients begin to think about areas of their lifestyle they may wish to address and how they might change.
4) Action planning call (30-40 minutes – with a nurse or dietitian). There is guidance on what this should cover. Discussion includes: going through their diagnosis of NDH and what it means, their blood test results, going through their risk factors, confirming with the patient that they have read the booklet, encouraging the patient to identify things that they might want to change; ensuring the action plan is specific, measurable, attainable, relevant and timely (SMART). Calculate 5% and 10% weight loss targets. Importance and confidence rating on what you set out to do; supporting patients to adjust unrealistic goals.
5) Referred to Care Call by Diabetes Team for further calls; the agreed goals and action plans are passed onto Care Call, to use during the telephone calls.

4b. Care Call Team

6) Telephone calls: Topics of discussion for each call (frequency described below in section 8) are 'loosely' planned in advance by the advisor (they are guided by the patient on the call so this isn't prescriptively planned), based on: the individual's goals and action plans; any measures from the patient record; choosing various standard scripts as appropriate. Advisors keep a record of what they have covered, so they can make sure, over time, they cover all the topics that might be useful with that patient.
7) Final call at nine months: Remind patients they should be called in by their GP for a repeat blood test at 12 months; symptoms of diabetes to watch out for; summarise progress.
8) Notify the GP of Care Call completion.

5. Who provides?

The action planning call is currently offered by the specialist dietitians and diabetes specialist nurses in the Diabetes Team.

All other follow-up calls are delivered by trained non-clinical health advisors. There are five health advisors at present (4.5 FTE), all of whom have many years of experience of this work. They are

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currently managed by a qualified nurse who joined Care Call from the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care Greater Manchester (CLAHRC GM). The health advisors are recruited from many backgrounds, including office work and health improvement. The most important qualities are an excellent telephone manner, good communication skills, empathy, and understanding of long term conditions. All health advisors play the same role in the NDH service: there are no specialities.

Training: Health advisors receive at least two months in-house induction training, including: participation in three groups for people with T2DM: the X-pert 6-week diabetes patient education programme; education sessions for newly diagnosed T2DM patients; and education sessions for insulin starters). Advisors are given educational materials, take part in telephone role-play calls, observe diabetes clinics, attend medication training with the Diabetes Team, and listen to calls by fellow advisors. All the health advisors have received training in motivational interviewing provided through AQuA.

6. How?

All the phone calls are made by the advisor to the patient. They are prearranged appointments. A patient has the same advisor throughout: this seems to be valued by patients, and builds trust. Information and health promotion resources are sent by post as required, tailored to individual needs. Calls are English language only.

7. Where?

Care Call is part of the Salford Healthcare division of Salford Royal NHS Foundation Trust's integrated care organisation. They are based in Summerfield House, in office accommodation.

8. When and how much?

- The programme consists of nine calls; an introductory call, an action planning call, six calls over six months, and then a final call at nine months. The calls are set at monthly intervals.
- The action planning call is 30-40 minutes in length.
- Follow-up calls last around 10-20 minutes. Advisors are assigned 30 minutes per call, to allow time for preparation, posting out resources and record-keeping.
- Advisors have capacity to make 12 calls per 7.5 hour working day.

9. Tailoring

There are a variety of scripts relating to NDH (including; portion control, weight loss, increasing activity, meal planning). The conversation is planned to meet the goals of the particular person, so is tailored, picking and choosing the scripts as guides on particular aspects of the conversation. Advisors emphasise flexibility and personalisation to individual circumstances to make material relevant and to foster a supportive relationship with the patient. They keep records on personal characteristics (disability, living situation) so they can adjust advice accordingly.

There is some flexibility to persist with patients who start to disengage. If a patient misses a call they are rebooked a new appointment. If someone misses two calls, they are discharged back to the GP, but if they re-contact Care Call at that point, they are accepted back onto the programme.

10. Modifications

Version IGR1 – 55 patients

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Referrals from seven selected GPs, supported by CLAHRC GM. Action planning call (by Diabetes Team), and followed by six phone calls at monthly intervals (by Care Call staff, based in the Diabetes Team).

The evaluation demonstrated, (i) some patients (views were mixed) said they felt they would like a face-to-face or group session, and (ii) some patients felt abandoned after six months. In response to these concerns, version 2 of the service included the option of a group session at the start, and a final call at nine months.

Version IGR2 – 200 patients
Referrals from all GPs, supported by CLAHRC GM. Patients were given a choice of either (i) ½ day group education session (by Diabetes Team) (n=100), or (ii) action planning call (by Diabetes Team) (n=100) at the start, followed by six months of phone calls plus a final call at nine months (by Care Call staff, based in the Diabetes Team).

Current version – commissioned as mainstream service in April 2014, running since January 2015, with referral routes for both primary and community care providers. Primary care referrals received from GPs, with help from a nurse facilitator (funded by CLAHRC GM; Hitachi Europe Ltd; and the NHS DPP). Direct access referrals from community teams. Action planning call (by Diabetes Team) followed by monthly phone calls for six months, plus a final phone call at nine months (by Care Call staff now independent of the Diabetes Team). Education and action planning is provided by telephone to individual patients. There is no longer an initial face-to-face option.

Planned changes

1) Action planning call to be done by Care Call staff, instead of Diabetes Team. Care Call has historically been an integral part of the Diabetes Service, and Care Call continues to provide a diabetes support service to patients with type 2 diabetes. For patients with NDH, the service will in future be delivered wholly by the health advisors in the Care Call team to allow specialist resources to focus on patients diagnosed with diabetes. Diabetes nurses have previously undertaken the initial action planning calls with patients. Their role in reviewing the NDH scripts is currently under discussion. The Care Call staff are currently undergoing training to obtain the Royal Society of Public Health (RSPH) level 2 certificate in understanding behaviour change which will enable them to undertake action planning calls. They will also shadow the diabetes dietitian who currently completes the action planning calls.

   Interview respondents varied in whether they considered health advisors to be capable of delivering more formal action planning or whether this required more specialist (potentially clinical) expertise or experience. The health advisors themselves are confident about their ability to provide the full service (including the action planning call) in terms of skills, although they have some concerns about capacity. The primary drivers for reducing input from diabetes specialist nurses were the need to preserve limited specialist capacity for patients who have diabetes, enabling patients to connect with one worker throughout the whole process, and the appropriateness of health advisor skills to delivering behavioural or lifestyle focused interventions.

   Some respondents suggested that continued provision of a group education session, as an alternative to the action planning call at the start, would have been helpful, to increase

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patient choice, cater to different patient preferences and to provide more visual information (for example around food portion sizes). The service does provide signposting to other group activities or support groups for those who wish to take these up.

2) IGR3, a blended service of online interactive health coaching materials developed by Hitachi Europe Ltd, in combination with telephone calls, is currently being trialled alongside Salford IGR Care Call. IGR3 provides patients with an online 'dashboard' to track their progress and communicate with their health advisor through a web interface. Depending on the results of the trial, this may be made available as a future option for patients.

11. How well? - fidelity

The manager is located in the same office as those delivering calls, which may act as a form of quality monitoring. In terms of more formal monitoring, health care professionals such as the manager, diabetes dietitians and diabetes specialist nurses can listen into some of the calls. There is currently no facility to tape calls and listen to a random sample. Calls could then be evaluated for fidelity to the pathway, and against standard measures of motivational interviewing, such as BeCCI[14] or MITI[15].

12. How well? – acceptability and challenges

Care Call staff are enthusiastic and enjoy the job. Service managers reported that health advisors are well suited to their current role and can form effective relationships over the telephone. Telephone provision was considered to allow greater flexibility in contact with patients and also potentially enable a more honest dialogue to take place. The challenges relating to the action planning call are discussed above.

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Section 4: Salford IGR Care Call – review of evidence

Salford IGR Care Call has been the subject of two previous evaluations. The first study, in 2010, included 55 patients, who received an action planning phone call (by a specialist diabetes nurse or dietitian), followed by 6 x 10-20 minute phone calls over 6 months[16, 17]. The second, in 2013, included 207 patients, who were offered a choice of either an action planning call (by the Diabetes Team), or a half day group session (by the Diabetes Team). In both groups, the initial contact was followed by 6 x 10-20 minute phone calls over six months, plus a final call at nine months[18].

We compare the results of those two evaluations, and data from qualitative research interviews, against evidence from the NHS DPP and elsewhere.

1. Evidence of Care Call effectiveness on outcomes

Note on confidence intervals (CIs)
Health researchers use data on a sample of people to estimate means (e.g. the mean HbA1c level) and proportions (e.g. the percentage who develop diabetes). We want to use those sample means or proportions to give us an idea of the levels of HbA1c or diabetes in the whole population. Confidence intervals help us to do that. The confidence interval is a range of values calculated from a sample that we can be confident will contain the true value of the population. For example, a 95% confidence interval is calculated so that if a study were repeated 100 times, 95 of intervals thus calculated from such samples would contain the true population value.

Public Health England (PHE) has recently completed a systematic review assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus (T2DM) in routine practice[8]. The review identified 36 eligible studies, 34 evaluating interventions based on diet and physical exercise, and two evaluating exercise interventions. The review included 18 randomised controlled trials (RCTs), 15 before-and-after studies, and three with other designs. Studies were conducted in Europe (n=17, of which eight in UK), the US (n=15), Australia (n=3) and Japan (n=1). The size of studies ranged from eight to 2,798 individuals in the intervention arm, with 33 of the 36 studies recruiting a minimum of 50 participants.

There was substantial heterogeneity between the studies in terms of setting, population, criteria used to identify diabetes risk, content of the interventions and follow up. There was variability in study quality, but overall, most studies scored fairly high, particularly the RCTs.

The review summarised the effect of pragmatic lifestyle interventions on outcomes, using meta-analysis. The outcomes addressed by the review were:

- Incidence of T2DM. Measured as incidence rate ratios (IRR) in RCTs; or incidence rate per 1 person-year (IR) in before-and-after studies.
- Weight change (kgs). (i) 12-18 months from baseline; (ii) 24-36 months since baseline.
- Fasting plasma glucose test change (mmol/l) (i) 12-18 months from baseline; (ii) 24-36 months since baseline.
- 2-hour plasma glucose change (mmol/l) (i) 12-18 months from baseline; (ii) 24-36 months since baseline.
- HbA1c change (%) at 12-18 months from baseline[1].

[11] HbA1c units can be reported in two ways, as IFCC (mmol/mol) or DCCT (%). In this report HbA1c units are reported as they were reported in the original sources (all %).

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All of the outcomes were summarised in two ways for the meta-analysis. First the authors present the results from randomised controlled trials, which summarises the effect of a lifestyle intervention on outcomes, after controlling for other influences on the outcome. Second they present the results of the before-and-after studies, together with the before-and-after change in the intervention arms of the RCTs. The findings of the systematic review are summarised in columns two and three of table 1, presented alongside the results from two before-and-after studies of Salford IGR Care Call.

The 2010 study of Salford IGR Care Call recruited 55 patients with NDH, who received an action planning phone call, followed by 6 x 10-20 minute phone calls over six months. Outcome measures (weight and fasting glucose) were collected at baseline, six and 18 months from baseline. All 55 patients completed the Care Call programme, 55 provided outcomes at six months and 40 at 18 months. The six month results are not included here, because the PHE systematic review did not assess outcomes at six months.

The 2013 study of Salford IGR Care Call recruited 207 patients with NDH who were offered a choice of either an action planning call, or a half day group session. In both groups, the initial contact was followed by 6 x 10-20 minute phone calls over six months, plus a final call at nine months. Outcome measures (weight and fasting glucose) were collected at baseline and 12 months from baseline. 105 patients completed the Care Call programme at the time the report was written (with others still receiving a service). It proved difficult to collect outcome measures, with before-and-after measures available for less than half of participants: weight (n=78); fasting glucose measures (n=102).

Table 1: Comparison of effectiveness of Care Call against PHE systematic review[8]

	RCTs	Before and after studies (including RCTs)	Salford Care Call 1 – 2010[16, 17] before and after N= 55	Salford Care Call 2 – 2013[18] before and after N=207
Incidence of T2DM IRR (95% CI) 17 studies (12 RCTs)	IRR 0.74 (0.58, 0.93)	IR 0.08 (0.05, 0.11)	IR 0.033 (0.004,0.155) N=40	IR 0.147 (0.085,0.231) N=102
Weight (kg) at 12-18 months from baseline Mean (95% CI) 38 studies (20 RCTs)	-1.57 (-2.28,-0.86)	-2.46 (-2.99,-1.94)	-2.81 (-4.42, -1.20) 18 months N=40	-4.3 (-5.6, -3.0) 12 months N=78
Weight (kg) at 24-36 months Mean change (95% CI) 12 studies, all RCTs	-1.26 (-2.35, -0.18)	-2.13 (-3.21, -1.05)	Not collected	Not collected
Fasting glucose (mmol/l) at 12-18 months Mean change (95% CI) 27 studies (16	-0.06 (-0.11, 0.00)	-0.09 (-0.14, -0.04)	-0.29 (-0.51, -0.07) 18 months N=40	-0.07 (-0.24 to 0.10) 12 months N=102

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RCTs)				
Fasting glucose (mmol/l) at 24-36 months Mean change (95% CI) 9 studies (8 RCTs)	-0.07 (-0.13, -0.02)	0.01 (-0.10, 0.12)	Not collected	Not collected
2-hour glucose (mmol/l) at 12-18 months Mean change (95% CI) 15 studies (10 RCTs)	-0.28 (-0.57, 0.00)	-0.11 (-0.44, 0.22)	Not collected	Not collected
2-hour glucose (mmol/l) at 24-36 months Mean change (95% CI) 8 studies (7 RCTs)	-0.52 (-1.05, 0.01)	-0.28 (-0.67, 0.10)	Not collected	Not collected
HbA1c (%) at 12-18 months Mean change (95% CI) 11 studies (9 RCTs)	-0.04 (-0.07, -0.01)	-0.12 (-0.18, -0.06)	Not collected	Not collected

Both studies used the fasting glucose results to make a tentative estimate of the incidence of type 2 diabetes, and these results are presented in table 1. Diagnosis of type 2 diabetes is a clinical decision based on other evidence alongside the blood test, so these results need to be treated cautiously. It is not clear whether the incidence rates reported in the systematic review are based on blood results, or a more complete diagnosis.

i. Incidence of type 2 diabetes
The systematic review found that, on average, the incidence of T2DM among patients attending a lifestyle programme was 75 cases per 1,000 person-years (95% CI 50 to 110, n=29 studies). During the Care Call 1 study, the comparable diabetes incidence rate was 33 cases per 1,000 person-years (95% CI 0.4 to 1,550, n=40). During Care Call 2, the diabetes incidence rate was 147 cases per 1,000 person-year (95% CI 85 to 2,310, n=102). The wide confidence intervals and the loss to follow up in both studies make it difficult to come to any firm conclusions in comparing effectiveness of Care Call to the systematic review in terms of reducing the incidence of T2DM.

ii. Weight at 12-18 months
The systematic review evidence from RCTs indicates that the mean weight loss among patients attending a lifestyle programme, compared to those not attending a programme, was 1.6kg (95% CI 0.86 to 2.28kg). Evidence from the before-and-after studies indicates a mean weight loss of 2.5kg (95% CI 1.94 to 2.99kg). We would expect the weight loss in before-and-after studies to be higher than in RCTs, because the RCT reports the difference

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between treatment and control groups, and it is plausible that some patients diagnosed with NDH in the control groups will make an effort at lifestyle change without support.

During the Care Call 1 study, the mean weight loss at 18 months was 2.8kg (95% CI 1.2 to 4.42kg, n=40). During Care Call 2, the mean weight loss at 12 months was 4.3kg (95% CI 3.0 to 5.6kg, n=78) n=102). As illustrated in figure 1, the weight loss during Care Call 1 is comparable to the evidence from national before-and-after studies, but with a wider confidence interval. The weight loss in Care Call 2 exceeds the national evidence, but it is based on a small fraction of the original sample (78 out of 207) and we cannot make any conclusions about the weight loss in the missing patients.

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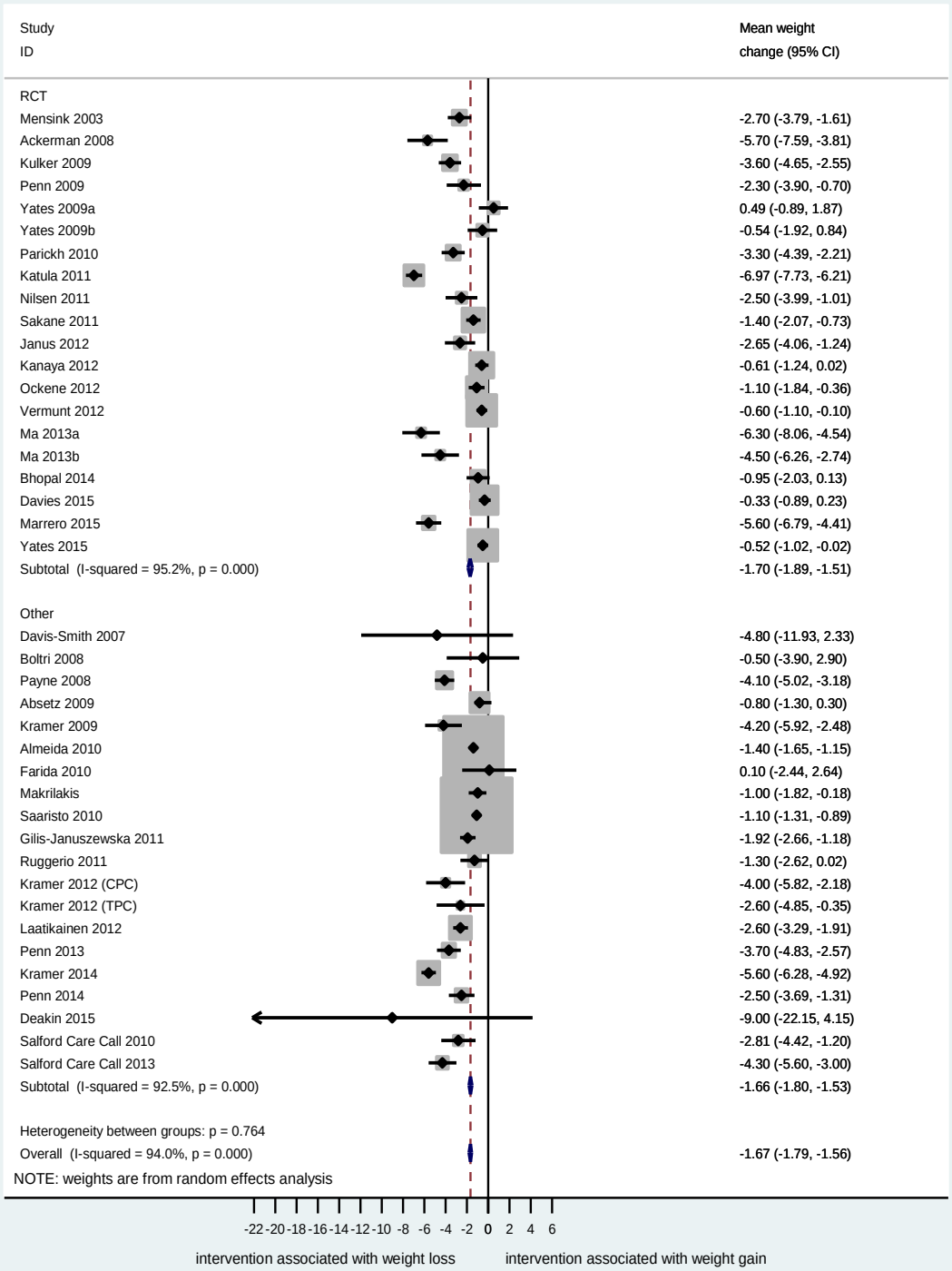
Figure 1: Before and after forest plot showing weight change at 12-18 months in study arms which received lifestyle intervention[8], with addition of two Salford Care Call studies. Studies which are left of the centre line are studies which showed a positive effect



iii. Fasting glucose at 12-18 months

The systematic review evidence from RCTs indicates that there is minimal evidence that attending a lifestyle programme achieves a reduction in fasting glucose. There was a small mean reduction of 0.06mmol/l, but the 95% CI includes zero (0 to 0.1mmol/l). Evidence from

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the before-and-after studies indicates a small mean reduction in fasting glucose of 0.09mmol/l (95% CI 0.04 to 0.14mmol/l). We would expect the change in before-and-after studies to be higher than in RCTs, because the RCT reports the difference between treatment and control groups, and it is plausible that some patients diagnosed with NDH in the control groups will make an effort at lifestyle change without support.

During the Care Call 1 study[17], there was a small mean reduction in fasting glucose at 18 months, of 0.29mmol/l (95% CI 0.07 to 0.51 mmol/l, n=40). This is a similar effect to the before-and-after studies in the systematic review, but with a wider confidence interval. During Care Call 2, there was no statistically significant change in fasting glucose. The results of study 2 are based on a half of the original participants, 102 out of 207, and we cannot make any conclusions about the fasting glucose changes in the missing patients.

2. Systematic review – Aziz et al 2015

The first Salford Care Call Study (2010) was included in a systematic review by Aziz et al (2015) of 38 real-world diabetes prevention programmes[19]. It reported that although high-intensity diabetes prevention interventions resulted in increased weight loss outcomes, the high uptake of lower intensity interventions (i.e. less time spent with the patient), could still impact on diabetes risk, despite lower weight loss outcomes. In other words, they state that diabetes prevention can be achieved through lower resource intensive and thus more cost effective interventions, through decreasing intensity and increasing uptake.

The authors assessed the programmes using the PIPE impact metric[20], which compared health improvement programmes on four elements: **P**enetration of the programme into the population of interest; **I**mplementation of the proposed set of services; **P**articipation in the programme; and **E**ffectiveness in generating expected outcomes.

The assessment of Salford IGR Care Call was as follows:
Penetration: Insufficient information was provided to assess this.
Implementation: Care Call did not fare well in terms of frequency (low) or duration (moderate), but the fidelity was rated high.
Participation: The participation (retention) rate was high (55 out of 55 completed the pathway). This was unusual: only seven (18%) studies achieved high participation rates.
Effectiveness: The weight loss reported by Care Call was assessed as moderate, which compares favourably with other studies: half the studies scored low and only a fifth scored high. There was insufficient information to score Care Call on the other outcomes.

Table 2: Assessment of Care Call according to the PIPE impact metric, data taken from a systematic review of DPPs[21]

PIPE element		Care Call Study 1	Overall scores
Penetration (no. of individuals reached, as proportion of the target population)		NAC	76% of studies did not report penetration
Implementation	Frequency (no. of sessions per year – phone counts 0.5)	Low	34% scored high
	Duration (months)	Moderate	39% scored high (over 12 months)
	Fidelity (use of a	High	71% scored high

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	standard curriculum and quality assurance)		
Participation (no. enrolled in the intervention as proportion of number invited)		High	7 (18%) of studies had a high participation rate.
Effectiveness	Success rate	NAC	
	Weight loss	Moderate	6 (19%) scored high; 10 (31%) moderate; 16 (50%) low
	Risk reduction (absolute/relative)	NR	82% studies did not report this

NAC = not able to calculate
NR = not reported

3. Programme content and delivery

NHS England, Public Health England and Diabetes UK have recently announced the national roll out of 'The Healthier You: The NHS Diabetes Prevention Programme', making 20,000 places available in 27 areas of the country from April 2016, expanding to 100,000 places nationally by 2020. Four providers (Reed Momenta, Pulse Healthcare Limited – trading as ICS Health and Wellbeing, Health Exchange CIC and Ingeus UK Limited) have been chosen to work with local health services to deliver diabetes prevention services.

The primary objective of the NHS DPP is to support patients with NDH to lower their risk of progression to type 2 diabetes and/or to delay the onset of disease and its complications by promoting weight loss and reducing glucose parameters (HbA1c/fasting glucose levels) [22].

'Those referred will get tailored, personalised help to reduce their risk of type 2 diabetes including education on healthy eating and lifestyle, help to lose weight and bespoke physical exercise programmes, all of which together have been proven to reduce the risk of developing the disease[23].'

A comparison of Salford IGR Care Call with the services currently being commissioned by NHS DPP is presented in table 3.

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Table 3: Comparison of Salford IGR Care Call with NHS DPP recommendations

	NHS DPP recommendations[a]	Salford IGR Care Call
Objectives	Aim is to support people with non-diabetic hyperglycaemia to lower their risk of progression to type 2 diabetes by promoting weight loss and reducing glucose parameters (HbA1c/fasting glucose levels)	Salford IGR Care Call shares these aims
Goals	Structured behaviour intervention to achieve • weight loss • dietary recommendations • physical activity recommendations.	Salford IGR Care Call uses these goals
Underpinning approach/theory	The intervention should be grounded in behaviour change theory, explicit about what techniques are being used, and should support sustained behaviour change, including: • goal setting (which should occur frequently) • self-monitoring • clear, targeted, and high quality risk communication. Family or peer support should be accommodated wherever possible.	Salford IGR Care Call staff are trained in motivational interviewing. The pathway includes goal setting, self-monitoring, risk communication, and can include informal family or peer support. We have not assessed the effectiveness of Care Call in delivering this.
Delivery	Staffing: • sessions can be delivered by health professionals or non-health professionals • staff recruitment, training and development policies and practices ensure that staff have the appropriate competencies to deliver the intervention	Salford IGR Care Call is delivered by non-health professionals, with on-going training and development to ensure competence. Care Call staff are completing formal Level 2 RSPH training. It is not clear however if there are plans for ongoing competency assessment or refresher training at later stages.
	Predominantly face-to-face group sessions (10- 15 people), although may also include individual sessions (either in person or remotely). At present, limited evidence has been identified that examines the effectiveness of 'remote' approaches however they may for example be necessary in rural settings and with younger adults.	Salford IGR Care Call is delivered over the phone, and to individuals
	Frequency- Over a minimum of nine months patients will be offered at least 13 education and exercise sessions of one-to-two hours, at least 16 hours face-to-face or 1-to-1 in total.	Salford IGR Care Call service is over nine months, and includes an action planning phone call (30-40 mins), followed by 6 x 10-

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	NHS DPP recommendations[a]	Salford IGR Care Call
		20 minute phone calls over six months, plus a final 10-20 minute call at nine months. Total contact time is between 1 hour 40 minutes and 3 hours.
Content	A list of topics will need to be covered including (but not limited to): Dietary content: • UK dietary recommendations as detailed in the eatwell plate (increased intake of fibre, fruit and vegetables and oily fish, and decreased intake of saturated fat, sugar, salt and energy); • Participants should be encouraged to set achievable goals within identified areas for improvement; and • An energy intake goal should be set at an agreed level to achieve weight loss for individuals who are overweight. Physical activity content: • Participants should be supported to aim for more than 30 minutes a day of moderate exercises such as walking, 3-5 times a week with 20-60 minute bouts of aerobic fitness activity, and 2-3 days a week of strength training, as recommended by the UK Chief Medical Officer; • Individuals should be supported to incorporate active travel into their daily routine either through walking or cycling skills and group activities; and • Supervised exercise should be included and build gradually to increase exercise capacity.	Salford IGR Care Call includes content relating to both diet and physical activity. Goals are set according to the SMART framework to ensure feasibility. Diet information is consistent with NHS DPP recommendations. Patients are encouraged to be active but are not given set activity targets. There is no requirement for supervised exercise currently, but Care Call can support referral to supervised exercise programmes.

[a] NHS England and Public Health England. 2015. Consultation Guide: National Procurement for the Provision of Behavioural Interventions for People with Non Diabetic Hyperglycaemia[22]

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In many ways, Salford IGR Care Call meets with the recommendations for the commissioned service. Care Call shares the same objectives and goals as the NHS DPP. The service involves action planning and goal setting, and encourages self-monitoring of behaviour as described in the IGR Clinical Pathway. The pathway also refers to risk communication, based around the *'Are you at risk of Type 2 Diabetes?'* booklet which is sent to all patients prior to their first action planning call. Care Call staff, when interviewed, reported including family members in health discussions where appropriate (for example, discussing diet with a partner who is responsible for cooking) but there is no formal mechanism for involving family or peers.

The NHS DPP specifies a requirement that interventions are grounded in behaviour change theory and recommends an explicit description of the techniques used. Health advisors in Care Call are described as using "*advanced communication skills and elements of motivational interviewing during the telephone consultation e.g. use of open questions, clarifying, summarising etc.*" (IGR Clinical Pathway, October 2015). The Care Call staff have received local training in Motivational Interviewing (MI) techniques through AQuA. MI was developed to facilitate change in health related behaviours through adopting a patient-centred approach focused on negotiation and empathy. The approach includes specific techniques to explore reasons for and barriers to health behaviour change, consistent with the Transtheoretical Stages of Change model of health behaviour[24]. MI has been applied to a variety of health behaviours, including alcohol abuse, weight loss and medication adherence. It is therefore broadly consistent with the requirement for employing explicit techniques which are grounded in behaviour change theory. However, we did not assess fidelity to these techniques or to the approach directly. Furthermore, the Stages of Change model is not widely accepted within the field of behaviour change as an evidence-based model[25, 26]. We also were not able to systematically assess the content of the service against formal behaviour change frameworks or against the NICE Pathway for Behaviour Change (PH6 recommendations)[27]. Finally, consultation with an expert in behaviour change identified a potential tension between the employment of motivational interviewing and the more directive elements of the intervention (such as action planning and encouraging certain behaviours, for example exercise) as motivational interviewing should focus on individual self-directed goals rather than setting targets externally.

Service delivery by non-health professionals with suitable training meets the requirements of NHS DPP. In terms of ensuring fidelity, the programme is manualised, health information content adheres to scripts, staff training is provided and some calls observed. However, there is currently no formal assessment of fidelity, such as direct observation by an independent expert, or monitoring of a random sample of calls by an appropriate person against accredited criteria. The content of the sessions is similar to that suggested by NHS DPP, covering a similar range of topics (except for exercise sessions – see below).

The delivery of Care Call by telephone introduces a novel element, not covered by the national guidelines, specifically relating to whether motivational interviewing can be delivered by telephone. We therefore conducted a rapid review of available evidence (a review of existing systematic reviews) to assess available evidence for this. Multiple reviews have included studies that deliver MI by telephone, although these tend to be the minority in comparison to group or individual delivery[21, 28]. However, limitations in reporting and the small number of studies employing telephone delivery mean that no clear conclusions can be drawn regarding the relative effectiveness of telephone intervention against other modalities.

Based on discussions with a Health Psychologist with expertise in motivational interviewing, we also identified a need for further evidence regarding the background and training of professionals involved in delivery of motivational interviewing. The rapid review found it is unclear how much

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training is required for professionals to effectively use MI[29]. Proponents of MI recommend at least two days training with expert MI feedback and emphasise the importance of follow up reinforcement training and supervision. However, studies tend not to report the amount or duration of training received, making it difficult to draw conclusions about the potential impact of training on outcomes[25]. Wide variability in duration of training, whether follow up or 'booster' sessions are provided, and lack of detail in how training is described by individual studies limit the conclusions that can be drawn regarding how training can be most effective[30].

There are three areas where Salford IGR Care Call differs from the NHS DPP recommended service:

i. Supervised exercise sessions, as recommended by NHS DPP, are not included as an integral part of Salford Care Call. However, an NDH-specific exercise support programme is available to patients with NDH in Salford, delivered by Salford Community Leisure. Salford Care Call health advisors encourage patients to attend the exercise programme, and refer patients to it.

ii. Salford IGR Care Call is delivered remotely by telephone. There is currently a research project to investigate the effectiveness of an additional web-based service. All of the delivery is remote, without any face-to-face contact. NHS DPP recommends face-to-face delivery, and favours delivery in groups (although it is unclear whether behaviour change using motivational interviewing is effective in group settings).

iii. Salford IGR Care Call is delivered over the same duration as the NHS DPP recommends (nine months), but it offers less contact time than the NHS DPP recommends. Care Call includes a 30-40 minute action planning phone call, followed by 6 x 10-20 minute phone calls over six months, plus a final 10-20 minute call at nine months (as described more fully earlier in the report). In total, over nine months, patients have between 1 hour 40 minutes and 3 hours of one-to-one contact with a health advisor, if they receive the full 'dose' as anticipated. This is substantially less than the 16 hours face-to-face contact time recommended by NHS DPP: 13 education and exercise sessions of 1-2 hours. However, all the contact time with Care Call is at an individual level and tailored to the needs of that individual. Salford residents with NDH who choose to attend both Care Call and the Exercise programme may achieve the recommended contact time, but we have not undertaken an evaluation of the exercise programme, so cannot confirm this.

It is important to note that the content of the NHS DPP service has been derived from the systematic review undertaken by Public Health England (PHE)[8], followed by a discussion with experts. Using a sub-group analysis, the review authors conclude that a larger effect size was found for interventions that included the elements listed in table 3. The sub-group analysis is an attempt to identify the important elements within the interventions that had the largest effect. However, some caution is needed in interpreting the results. Firstly, it involved multiple testing of many elements against many outcomes, and some of the findings of statistical significance may be due to chance. Secondly, in every case, the identified elements were shown to have a beneficial effect on one or two of the outcomes rather than all the outcomes. We can illustrate this with the example of session length. Compared with sessions of under an hour (two studies), sessions of 1-2 hours (seven studies) are associated with an extra 1.18kg weight loss, but studies of over two hours (six studies) show no difference. Study length had no impact on T2DM incidence, fasting glucose or two hour glucose. This approach has been challenged in a recent paper[31].

4. Recruitment and retention

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Recruitment and retention will be discussed in the next report.

5. Evidence for telephone delivery

One systematic review has been completed on the impact of telephone interventions on glycaemic control in diabetes patients[32]. This review was not picked up by the PHE review, which focused only on patients at risk of diabetes. The review identified five trials, with a total of 953 patients. The studies were very variable in time period (3-12 months), frequency (2-16 calls) and duration (9-15 minutes). Both phone call intervention and standard clinical care varied greatly from trial to trial in their content. A meta-analysis of the five studies found no evidence that a telephone intervention affects glycaemic control: the mean reduction in HbA1c was 0.38% (95% CI -0.16 to 0.91%). The timing of the measurement is not specified. No other outcomes were assessed.

Since that review, an RCT has been reported on the effects of a lifestyle intervention for patients at risk of T2DM[33]. The intervention consisted of two individual face-to-face sessions, followed by 12 telephone calls and five optional group workshops (up to 19 contacts, up to 15 hours), delivered in the US to a lower socio-economic status community sample. The lifestyle intervention included goal setting, action planning, using motivational interviewing techniques, compared to a wait-list control group who received usual care. At six months from baseline, the intervention group lost 1.9kg more than the control group ($p<0.05$), but by 12 months there was no difference in weight. The intervention had no effect on fasting glucose at either six or 12 months.

An RCT has compared the effect of individual versus conference telephone calls for patients at risk of T2DM[34]. The study did not find a difference in weight loss at six months and one year post baseline. At two years, the group who received conference calls on average lost 4kg more than those in the individual group. However, the retention was poor: of 257 patients recruited to the study, 135 completed the two year follow-up. The trial compared two telephone interventions, without any non-telephone control, which does not allow any conclusion on the overall effect of telephone delivery.

Salford IGR Care Call has developed over time from the Pro Active Call Centre Treatment Support (PAACTS)[35] randomised controlled trial, which assessed a lifestyle intervention in Salford for patients with established diabetes. The PACCTS trial showed that the telephone intervention was acceptable to patients, and had a small positive effect on HbA1c, a reduction of 0.3% compared to usual care. This was less than the 1% reduction which is regarded as being clinically important[36].

Overall, there is inconclusive and unclear evidence on the effect of delivering a lifestyle intervention by telephone to patients at risk of diabetes. The only systematic review indicates that there is no evidence for any effect of telephone delivery on HbA1c (reduction of 0.38%; 95% CI -0.16 to 0.91%)[34]. By comparison, the recent systematic review of pragmatic lifestyle interventions for this patient group, which included mainly face-to-face interventions, reported a very small average reduction in HbA1c at 12-18 months of 0.04%, with a 95% CI or 0.01 to 0.07%. There is no clear evidence that telephone support has any effect on HbA1c, and face-to-face intervention has a very small effect, less than what is regarded as clinically important[36]. The review for face-to-face delivery also reported (at 12-18 months) a reduced incidence of diabetes and mean weight loss of 1.6kg, but found no evidence of an effect on fasting glucose or two hour glucose[8]. There is no evidence that face-to-face has a greater effect on HbA1c than telephone delivery: the confidence interval for telephone lies within the confidence interval for face-to-face. Unfortunately, the systematic review of telephone delivery does not report on weight loss or diabetes incidence, which does not allow an adequate comparison of the reviews of telephone and face-to-face. It would be interesting to repeat

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the systematic review of telephone delivery and examine other outcomes, including weight loss and diabetes incidence.

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Section 5: Key findings

We have described Salford IGR Care Call, using the TiDIER framework. We have reviewed Salford IGR Care Call against relevant academic literature and the specifications of the NHS DPP. The findings are summarised below:

1. **Content and Delivery**

Salford IGR Care Call meets with the NHS DPP national specification in terms of its objectives and goals. Care Call employs motivational interviewing and so is broadly consistent with the requirements of NHS DPP to be based on explicit behaviour change theory, although we did not evaluate fidelity to a model of behaviour change or assess the content in relation to formal behaviour change frameworks (for example, the Behaviour Change Wheel[37]). There is also uncertainty regarding whether telephone delivery of motivational interviewing is effective and what the explicit training requirements are for staff to be considered competent in motivational interviewing. Current evidence from systematic reviews does not allow us to draw conclusions about this.

The Care Call pathway includes goal setting, self-monitoring and risk communication, as recommended by NHS DPP. It can include informal family or peer support, although there is nothing formal in place on this. Delivery is by non-health professionals, with training for the role. The content of the phone calls is similar to that suggested by NHS DPP, with a focus on diet and exercise. There are three particular areas where Salford IGR Care Call differs from the NHS DPP recommended service:

a. Supervised exercise sessions, as recommended by NHS DPP, are not included as an integral part of Salford Care Call. However, an NDH-specific exercise support programme is available to patients with NDH in Salford, delivered by Salford Community Leisure. Salford Care Call health advisors encourage patients to attend the exercise programme, and refer patients to it.

b. Salford IGR Care Call is delivered remotely by telephone, and there is currently a research project to investigate the effectiveness of an additional web-based service. All of the delivery is remote, without any face-to-face contact. NHS DPP recommends face-to-face delivery, and favours delivery in groups.

c. Salford IGR Care Call is delivered over the same duration as the NHS DPP recommends (nine months), but it offers less contact time than the NHS DPP recommends. Care Call includes a 30-40 minute action planning phone call, followed by 6 x 10-20 minute phone calls over six months, plus a final 10-20 minute call at nine months. This is a total of between 1 hour 40 minutes and 3 hours, substantially less than the 16 hours face-to-face contact time recommended by NHS DPP: 13 education and exercise sessions of 1-2 hours. However, all the contact time with Care Call is at an individual level and tailored to the needs of that individual. Salford residents with NDH who choose to attend both Care Call and the Exercise programme may achieve the recommended contact time, but we have not undertaken an evaluation of the exercise programme, so cannot confirm this.

2. **Evidence for telephone delivery**

Research on telephone delivery of lifestyle interventions to prevent diabetes is scarce. There is no evidence that a lifestyle intervention delivered by telephone has an effect on HbA1c in patients with

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diabetes[30]. By comparison, face-to-face lifestyle interventions have a very small effect on HbA1c, a reduction of 0.04%[8]. This does not provide evidence that face-to-face has a greater effect on HbA1c than telephone delivery: the confidence interval for telephone lies within the confidence interval for face-to-face.

Unfortunately, the only systematic review of telephone delivery is in diabetes patients. It reports only on HbA1c outcome, and does not report the effect on weight loss or diabetes incidence, which prevents an adequate comparison of the impact telephone and face-to-face delivery.

3. Effectiveness

Two research studies have examined the effectiveness of Salford IGR Care Call[16, 18]. The 2010 study recruited 55 patients to Care Call and followed them up at 18 months (n=40). The 2013 study recruited 207 patients and followed them up at 12 months (n=78 to 102, for different outcomes). We have compared the results of these studies to the results included in PHE's systematic review of pragmatic lifestyle interventions.

We need to be cautious about interpretation of the results: both Care Call evaluations reported substantial loss to follow up. In particular, the 2013 study collected before-and-after results for less than half the participants. We cannot make any assumptions about whether the same results would have been seen in the missing patients.

i. Diabetes incidence

We were unable to make any meaningful comparison with the studies in the systematic review, due to the small study size and the low incidence of the outcome.

ii. Weight

The mean weight loss was 2.8kg in the 2010 study 4.3kg in 2013. This amount of weight loss is consistent with that reported in other before and after studies included in the NHS DPP systematic review.

iii. Fasting glucose

There was a very small mean reduction in fasting glucose of 0.29mmol/l in the 2010 study, and there was no evidence of a change in 2013. This is consistent with before and after studies included in the NHS DPP systematic review, which found no change in fasting glucose results.

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Section 6: Limitations

1. We did not have time to perform a full systematic review regarding whether MI can be delivered by phone and what the training requirements are, although the rapid reviews conducted suggest that there is little available evidence to draw firm conclusions regarding this.

2. We did not conduct formal observations of the Care Call service and so concordance with NHS DPP is based on an evaluation of the content of the service, according to available documentation and interviews with staff. We are unable to draw any conclusions regarding fidelity of delivery of the service in practice.

3. The evidence for telephone delivery of lifestyle interventions for patients at risk of diabetes is very sparse, so our study conclusions are based on shaky ground. A robust study of effectiveness is needed and this could include (i) a systematic review of telephone delivery of lifestyle interventions in similar populations; and (ii) an RCT comparing the effect on diabetes incidence, weight change, and HbA1c of Care Call against usual care or face-to-face delivery.

4. We have not observed any individual advice sessions to assess the fidelity of the delivery. Nor have we evaluated the fidelity of the service to any particular model of behaviour change or assessed the content in relation to formal behaviour change frameworks (for example, the Behaviour Change Wheel[37] or NICE behaviour change guidance[26]). Such assessment is currently being planned in Salford, as part of an accreditation process required by the NDPP.

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Section 7: Appendices

Appendix 1: The TIDieR (Template for Intervention Description and Replication) Checklist:

TIDieR
Template for Intervention Description and Replication

Information to include when describing an intervention and the location of the information

Item number	Item
1.	**BRIEF NAME** Provide the name or a phrase that describes the intervention.
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.
8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.

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9.	**TAILORING** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.
10.	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.
12.	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.

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Appendix 2: Care Call interview topic guide

The purpose of the interview is to develop a clear understanding of Care Call, so we can describe it to someone else.

	TIDieR item
Introductions - The purpose of the interview is to develop a clear understanding of Care Call, so we can describe it to someone else - The role of respondent in relation to Care Call	
Identify the different components of the intervention - Why was this overall approach chosen? Why those components? - Why chosen over other alternatives? - Goals - Based on any theory or approach or techniques - Mechanism of action (active ingredient)	2
(ingredients) - Describe the materials used in Care Call – scripts, documents, other materials - Are they available? Open access?	3
(methods) - Describe the processes, activities, procedures - The sequence of steps followed from referral received to discharge - Include any other add-on activities	4
Who are the intervention providers? (think about the caller, but also any support or supervisory or clinical roles) - Number, disciplinary background, skills, expertise, experience - Specific training - Any competence assessment - Part of a normal role, or specially recruited - Incentives	5
Modes of delivery (think about telephone, but is there also any face-to-face or postal?) - Features of delivery – who initiates? Interaction	6
Where? - Location. - Infrastructure, equipment, consumables	7
When and how much? (think about what is planned and what is received) - Number of calls - Over what period - Duration of calls	8
Tailoring. Does everyone receive the same intervention, or is it planned to be personalised? - If so, what, why, when and how? - What are the decision points and rules?	9

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Modifications over time. Have you changed the intervention and if so, how can this information help others in the future?	10
Any strategies in place to measure fidelity of delivery?	11
Perception of the interviewee of: - the acceptability of the Care Call model to staff delivering it, - any challenges to implementing it (e.g. are staff trained in the specific techniques? does it need staff with a certain background?)	12
Where else should we look for information about Care Call? - Written documents? - Anyone else we should talk to?	

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Appendix 3: 'My Plan' goal setting template

Salford Royal NHS Foundation Trust
University Teaching Trust

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How to complete 'My Plan'

1. Please read the booklet 'Are you at risk of Type 2 Diabetes'
2. Use the information in the booklet to help you to identify the areas you would like to change about your Eating Habits and Physical Activities. Complete below
3. The Specialist Nurse/Dietitian will discuss your 6 month weight loss goal at your appointment, if appropriate

My Plan

Name: _____

Weight/Date: _____

My 6 month weight loss goal: _____

My action plan to reduce my risk of developing Type 2 Diabetes is:-

Eating Habits – Changes I would like to make:

1. _____
2. _____
3. _____

Physical Activity – Changes I would like to make:

1. _____
2. _____
3. _____

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Appendix 4: IGR telephone pathway

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Appendix 5: Useful links

Advancing Quality Alliance (AQuA)
https://www.aquanw.nhs.uk/

Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester (GM)
http://clahrc-gm.nihr.ac.uk/

Diabetes UK
https://www.diabetes.org.uk/

Hormone and Metabolic Research: IMAGE Guidelines
http://www.hadassah.org.il/media/1903188/PrimaryPreventionofType2DiabetesisAdvancing.pdf

Leicester Diabetes Centre
http://www.leicesterdiabetescentre.org.uk/

National Institute for Health and Clinical Excellence (NICE)
https://www.nice.org.uk

PLANS
http://www.plansforyourhealth.org/

Public Health England
https://www.gov.uk/government/organisations/public-health-england

Salford Heart Care
http://www.salfordheartcare.co.uk/

The Healthier You: NHS Diabetes Prevention Programme (NHS England)
https://www.england.nhs.uk/ourwork/qual-clin-lead/diabetes-prevention/

X-PERT Health
http://www.xperthealth.org.uk/

World Cancer Fund
http://www.wcrf-uk.org/

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