



In your Element Ltd



Innovation Ulster

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Outcome Report for the following Pilot Intervention (Date 28th September 2015)

Title:

Reversing Type 2 Diabetes Risk : a pilot evaluation combining ‘take action to prevent Type 2 Diabetes toolkit’ with the support of an digital tool ‘My Social Prescription®’ and screening for psychological barriers in those at risk of developing Type 2 Diabetes Mellitus (Type 2 DM)(BMI>30)

Background:

Pre-diabetes, also commonly referred to as borderline diabetes, is a metabolic condition and a growing global problem that is closely tied to obesity. If undiagnosed or untreated, pre-diabetes can develop into type 2 diabetes, which whilst treatable is currently not fully reversible. The increasing number of new cases of pre-diabetes presents a global concern as it carries large scale implications towards the future burden on healthcare, as statistics have shown between 2003 and 2011, the prevalence of pre-diabetes in England had tripled, with 35.3% of the adult population, or every 1 in 3 people having pre-diabetes (Diabetes in the UK 2001: Key statistics on diabetes). The World Health Organisation (WHO) has estimated that such chronic conditions will account for approximately three-quarters of deaths in the developing world by 2020. In this regard the increasing amount of evidence of overweight and obesity could be an emerging public health problem in the low and middle-income communities (F.Abthai et.al 2009).

The NHS (National Health Service) spends a considerable amount of money treating patients with long term conditions. A long term condition is a condition that there is no cure for; they can only be managed through drugs or alternative treatment regimens. These types of conditions can range from

diabetes, arthritis, chronic obstructive pulmonary disease and hypertension to name a few (Kings fund, 2012). Over a quarter of England's population (15.4 million) have a long term condition, with a number of these people having multiple long term conditions. People with these conditions use a significant proportion of the health care services (50 per cent of all GP appointments and 70 per cent of days spent in hospital beds).

Obesity is a preventable risk factor for diabetes mellitus and it has been found that the risk of developing diabetes mellitus can be reduced if effective measures are taken to control obesity (Abthai et.al 2009). However, obesity is and continues to be a global public health challenge. It causes an increase in numerous chronic diseases and therefore is characterised as a global health crisis (Kraak. V 2010). For many years the key tasks which concern the prevention and treatment of obesity have been diet and physical activity (Holmes et.al 2010). Anne Dee et.al (2015) have stated that the prevalence of obesity has continued to increase worldwide and this is putting the populations health at risk as well as creating a wider societal cost regarding productivity loss and premature mortality. They also found that healthcare costs of overweight and obesity in 2009 were estimated at £127.41 million for Northern Ireland and the main causes of these healthcare costs were cardiovascular disease, type II diabetes, colon cancer, stroke and gallbladder disease.

A prevention method is better than a cure (Take action to prevent diabetes: A toolkit for the prevention of type 2 diabetes in Europe). National and governmental policy suggests that there is a responsibility for the diabetes epidemic to be addressed, yet this goes beyond the healthcare systems control as behaviour changes are the responsibility of the individual and only supported by healthcare providers (Take action to prevent diabetes). The epidemic predictions are that by 2030, there may be close to 439 million people globally with type 2 diabetes, setting the predicted pre-diabetes figures at 472million by 2030 (IDF) Atlas, as cited in Uusitupa et al, (2011).

Tuumilehto,, Schwarz, Lindstrom, J., (2011), concluded that the pattern of increasing diabetic patients needs to be stopped through the implementation of evidence based recommendations on the prevention of type 2 diabetes. He stated political support is key with the development of a prevention plan for type 2 diabetes in all countries, along with vivid changes made within the health sector stating, "The most urgent issues is to use people who have training in lifestyle management, diet, physical activity, psychological issues etc.".

I was also documented that the research targeted towards preventing type 2 diabetes needs to be expanded, as although trials so far have provided a decent basis for this field, there is much more research to be conducted in various societies and cultural settings showing programmes being implemented in communities and in real-life settings. A diabetes prevention programming (DPP) was developed in the united kingdom by Yates et al (2012) called 'Walking away from diabetes'. Yates recognised that there was a shortage of research which explored the best ways to transfer DPP into

primary care routine in the UK through diet/exercise and healthy lifestyles to reduce the risk of diabetes.

Mental health and Diabetes

It has been estimated that mental health problems cost the UK almost £100 billion each year and this has been predicted to double over the next 20 years (Department of health: Achieving better access to mental health services by 2020). It has been found that people with mental illnesses die 15-20 years earlier than those without a mental illness, therefore it is essential to close the treatment gap between physical and mental illness (Simon Stevens NHS England). The mental health needs of people with long term chronic conditions has been found to go untreated which is causing a gap between a person's physical health and mental health, which is a lost opportunity in order to improve physical and mental health (Department of health, 2011). The department of health has therefore stated that a better integration of physical and mental health care will produce improved outcomes and improve the NHS funded services. They propose that early intervention models should be developed and they should provide treatment and support in the least restrictive settings close to home. An integrated approach is essential as one key area is the cost of managing a patient with diabetes and co-morbid depression. It is 4.5 times greater to manage a patient with diabetes and depression than the cost of managing a patient with diabetes alone. People must be assessed and treated holistically for their health problems, rather than providing separate services for physical and mental disorders (National Health Service 2014).

When planning a treatment regime for those with a chronic illness the main focus seems to lie solely on the biological factors but Morrison and Bennett (2009) state that careful consideration also needs to be given to the psychological factors also so a bio-psycho-social approach should be taken. The immune system and the neuroendocrine systems help the body's resistance to certain chronic illnesses such as cancer but these systems are what can be affected by stress and therefore can affect the body's ability to fight off, overcome or live with such chronic illnesses (Morrison & Bennett 2009).

Depression and associated symptoms establish a much greater risk for an individual developing type 2 diabetes and may accelerate the onset of diabetes complications (Dominique L. Musselman, Ephi Betan, Hannah Larsen and Lawrence S. Phillips). Such psychological barriers like depression help to maintain obesity (Byrne, Cooper & Fairburn 2003; Klem, Wing, McGuire, Seagle & Hill, 1997; Wing & Hill 2001). Tuumilehto & Puska (2011) clearly stated that the prevention of type 2 diabetes is associated with the prevention of obesity.

Research as such makes it clear that clients with pre-diabetes may need to be screened and treated for depression, anxiety, emotional overeating, low self-efficacy before being entered into a DPP. This study wishes to use the approved 'Lets Prevent Diabetes' programme toolkit to deliver the same

structured protocol but with additional supports to a novel trial. The current study is looking to determine whether or not this controlled educational programme combined with an online tool, “My Social Prescription” would support and enhance the delivery and maintenance of methods, offering what Tuumilehto et al (2011) refers to as a more personalised medicine approach. In addition to the trial aims to assess, identify and treat incident psychological barriers to success (such as depression, anxiety and binge eating using low intensity CBT), enhancing even further the effect of ‘Lets prevent diabetes’ programme, designed originally by Yates et al (2012).

The way in which health information is delivered could be a contributor to why chronic illnesses such as type II diabetes are constantly rising. As health care professionals have a legal obligation to inform their patients of their health risks, they are not intending to scare the patient but only to make them aware, however for some patients this can cause a negative impact reminding them that they are overweight and face potential life threatening illnesses. This can in turn cause psychological distress, anxiety or depression causing the patient to possibly binge eat and create a vicious cycle (Golden et al. 2008). Therefore the effectiveness of interventions to date is questionable (Cheetham et al. 2004).

Glasgow, et al (1999) acknowledge how type II diabetes is a public health problem with it having huge personal and societal costs if not treated or managed, therefore the way in which type II diabetes is treated or how it is prevented should not be left mainly to the individual but dealt with as the public health problem that it is. However Brink et.al (2002) stated that the responsibility of the individual’s health should also be transferred from the health practitioners to the individual themselves using interventions that will allow them to take more control of their health. According to Eyesenbach (2008) information technology will allow an individual to do this as it has grown so rapidly over the last decade. The key issue for preventing diabetes for patients, providers and healthcare systems is finding a way to deliver personal, affordable ways that can reach most a majority of the population (McKay et.al 1998). The internet can reach out to thousands of people 24 hours a day at a very low cost, yet most websites for support and information about type II diabetes have not been evaluated. There are high costs involved in the initial development of an online based intervention and this could be a key factor as to why there is little research in this field and why online interventions may not work (Jackson et.al 2006).

Tate et.al (2003) stated that weight loss programmes which are based online do appear to be quite promising for short-term weight loss but there was yet no research studying weight loss in individuals at risk of type II diabetes. Therefore a study was conducted to compare the effects of an internet weight loss program alone versus the internet weight loss programme along with behavioural counselling via email for one year to individuals which are at risk of developing type II diabetes. The study consisted of 92 overweight participants with an average age of 48.5 and an average body mass index (BMI) of 33.1. The participants were randomized to a basic internet programme or to an

internet plus behavioural e-counselling programme. The results showed that the behavioural e-counselling group had lost more weight at 12 months than the basic internet group, this significant weight loss will greatly improve the weight loss in adults at risk of developing type II diabetes. Tate et al (2003) shows that new approaches are needed to help reduce the prevention of type II diabetes. The Diabetes Prevention Programme (DPP) showed a 58% reduction in diabetes when carrying out a weight loss programme focusing on face-to face counselling over a period of 2.8 years, yet such an intervention would be very costly to run and would therefore be impractical as a long-term solution for reaching a large population. Tate et al (2003) also states how beneficial internet interventions could be in reducing these costly face-to-face interventions as this study showed the internet can deliver a behavioural weight loss program with desirable short-term results. The goal is not to completely rule out face-to-face interventions but to have a small combination of both interventions to begin with as internet interventions are suitable and affordable for long periods demonstrating a necessary model for treatment of chronic diseases.

Research conducted by Gold et.al (2007) focused on how internet weight loss programmes are now becoming more widely available and should be used as part of a standard treatment regime. The study was comparing a structured behavioural weight loss website where participants had access to a therapist via email and weight loss programmes online, to a commercial weight loss website. Their results showed that the structured behavioural weight loss website produced greater weight loss than the self-help commercial website. One point made by Gold et.al (2007) was the need for future research to incorporate a more structured behavioural program which is available in a commercial application.

McKay et.al (2001) concluded that interventions that were self-managed and internet based show great promise to increase the care of diabetes along with other chronic conditions and that there should be a bigger focus placed on ways to sustain interaction with interventions which are internet based and focusing on health problems. Jackson (2000) has also found that information technology has proven to be a substantial processing tool which has shown to improve the agenda of care for type 2 diabetes patients. Modern treatments of type II diabetes and other long term conditions involve treatments such as individualised education, active self-control, intense multiple dose treatment regimens as well as new insulin delivery technologies, however a large number of patients are still at risk of acute and possible long term complications (Diabetes control and complications trial 1993). Internet based interventions have been reported to improve access to health services as well as patients education, skills and even metabolic control (Jackson et.al 2006, McMahon et.al 2005, Blonde and parkin 2006). However most applications are aimed at a younger population who want to lose weight or remain fit, therefore there is a gap in the market for an online intervention tackling those who are hard to reach in a population. Researchers should be connecting and modifying the interventions to those that are hard to reach in the community (Bostinno 2012). This paper aims to

evaluate the effectiveness of a social prescription programme targeting overweight, pre-diabetic hard to reach groups in the community, along with empowering individuals to take control of their own health and mental well-being.

Rationale and Aim:

This is a trial of a novel intervention programme, the aim of which was to attempt to reverse Type 2 Diabetes, within a local community sample in Creggan area of Derry/Londonderry. This programme is novel as it has not piloted or trialed in Northern Ireland or Ireland before now. The intervention programme is a holistic, all-encompassing intervention to offer a tailored personalised care programme to help people reverse Diabetes risk. The intervention programme includes '*Take Action to Prevent Diabetes*' (the education component on diet and exercise facilitated by 'Well Care Coaches'), 'My Social Prescription®' (A digital platform that signposts people to programmes and services in their own communities. Across 3 main domains My Social Prescription concentrates on physical activity, diet/nutrition and mental health support to reduce the risk of chronic conditions such as Type 2 Diabetes. It has a built in tracking, evaluation & support & quality assurance for both Healthcare Professionals and clients). The trial aimed to target 'hard to reach' community groups who are at high risk of developing Type 2 Diabetes due to being overweight (BMI>30).

Measured and Intended Outcomes:

- Reduced Type 2 Diabetes risk score
- Reduced weight/BMI
- Increased mood and wellbeing (Reduce Depression & Anxiety Scores)
- Reduce Binge Eating Scores if evident

Methodology:

- The method used was *Pre- Post* pilot evaluation of a holistic intervention which included four novel elements
 - Re-assess those with BMI>30 for Pre- Diabetes risk
Those with Finrisc score above 12 up to 20 were entered into the pilot evaluation which consisted of:
 - 1) Baseline assessments by ‘Well care coaches’ including physical and psychological measurements.
 - 2) Individualised care plan using ‘Social Prescribing online tool’
 - 3) Well care coaches deliver the ‘Take Action to Prevent Type 2 Diabetes’ recognised Desmond tool kit
 - 4) For those with high scores on Phq9/GAD7, referral to Psychological Wellbeing Practitioners for identified psychological barriers

Measures:

- Diabetes risk measure
- Weight/BMI
- Waist Circumference
- mood and well being
 - 1) PHQ9 Depression
 - 2) GAD7 Anxiety
 - 3) Binge Eating

Information on the above was gathered at baseline, and at weeks, 4, 8 and 12. Time one being the baseline data, times 4 and 8 were the mid pilot monitoring data, and times 12 was the end of the pilot data.

Finnish Diabetes type 2 risk assessment

The Finnish Type 2 Diabetes Risk Assessment Form developed in 2001 is an example of an effective patient questionnaire and should be used as the basis for developing national questionnaires which take into account local factors. It has eight scored questions, with the total test score providing a measure of the probability of developing type 2 diabetes over the following 10 years. The reverse of the form contains brief advice on what the respondent can do to lower their risk of developing the disease, and whether they should seek advice or have clinical examinations.

The scores can then fall into 5 categories:

Lower than 7 – estimated 1 in 100 will develop the disease

7-11 – Slightly elevated, estimated 1 in 25 will develop the disease

12-14 - Moderate, estimated 1 in 6 will develop the disease.

15-20 – High, estimated 1 in 3 will develop the disease.

Higher than 20 – Very high, 1 in 2 will develop the disease

PHQ-9 Measure of Depression

The copyright for the PHQ-9 was formerly held with Pfizer, who provided the educational grant for Drs Spitzer, Williams and Kroenke who originally designed it.^[1] This is no longer the case and no permission is required to reproduce, translate, display or distribute the PHQ-9.

This easy to use patient questionnaire is a self-administered version of the PRIME-MD diagnostic instrument for common mental disorders. The PHQ-9 is the depression module, which scores each of the nine DSM-IV criteria as "0" (not at all) to "3" (nearly every day). It has been validated for use in primary care.

It is not a screening tool for depression but it is used to monitor the severity of depression and response to treatment. However, it can be used to make a tentative diagnosis of depression in at-risk populations - for example those with coronary heart disease or after stroke.

When screening for depression the Patient Health Questionnaire (PHQ-2) can be used first (it has a 97% sensitivity and a 67% specificity). If this is positive, the PHQ-9 can then be used, which has 61% sensitivity and 94% specificity in adults.

Depression Severity: 0-4 none, 5-9 mild, 10-14 moderate, 15-19 moderately severe, 20-27 severe. Validity has been assessed against an independent structured mental health professional (MHP) interview. PHQ-9 score ≥ 10 had a sensitivity of 88% and a specificity of 88% for major depression.

GAD-7 Measure of Anxiety

The GAD-7 originates from Spitzer RL, Kroenke K, Williams JB, et al; A brief measure for assessing generalized anxiety disorder. The score is calculated by assigning scores of 0,1,2 & 3 to the response categories of "not at all", "several days", "more than half of the days" and "nearly every day", respectively and adding together the scores for the seven questions.

Scores of 5,10 and 15 are taken as the cut off points for mild, moderate and severe anxiety respectively. When used as a screening tool, further evaluation is advised when the score is 10 or greater. Using the threshold score of 10, the GAD-7 has a sensitivity of 89% and a specificity of 82% for generalized anxiety disorder.

Binge Eating Scale

This is a sixteen item questionnaire used to assess the presence of binge eating behaviour indicative of an eating disorder. It was devised by J.Gormally et al. in 1982 specifically for use with obese individuals. The questions are based upon both behavioural characteristics and emotional, cognitive response, guilt or shame.

Each question has 3 to 4 separate responses assigned a numerical value. The score range is from 0-46.

Non binging: Less than 17

Moderate Binging 18-26

Severe bingeing: 27 +

The Key Interventions in this pilot are as follow

- 1) **‘Take Action to Prevent Type 2 Diabetes’** (Lindström et al, 2010). Please see this toolkit within the appendix.

This is a European based toolkit, which was launched in 2010, and rolled out across parts of Europe. It includes patient education and support in the areas of healthy diet and exercise, and runs for 12 weeks. To replicate the evaluation of this intervention, we decided to plan the baseline and follow up monitoring time point similar to this one. Take Action to Prevent Diabetes was able to show a reduction in Diabetes risk scores by almost 50%. We are aiming to incorporate this tool, but add to it and increase efficacy further.

- 2) **Social Prescribing digital tool (My Social Prescription®)**

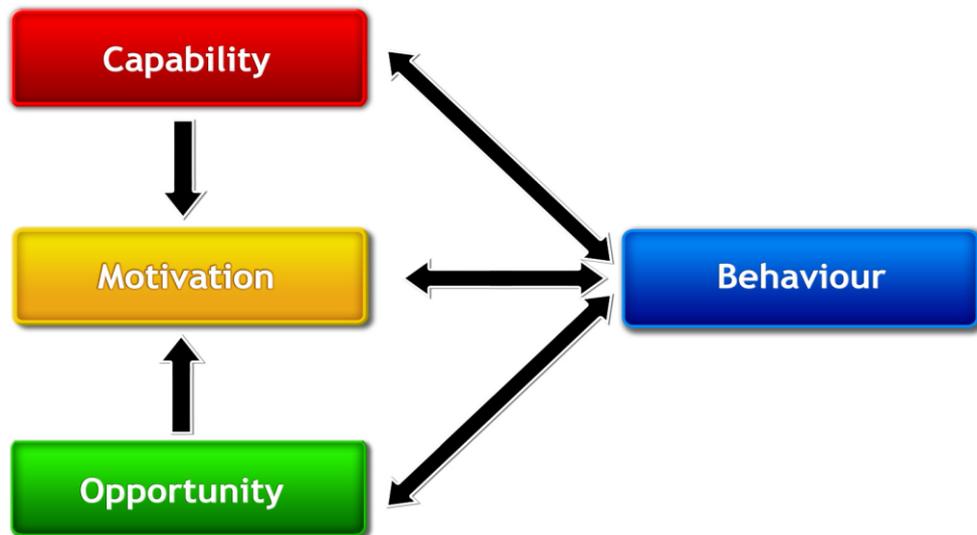
Digital signposting technology which tracks support and engagement, delivering measurable health benefits for those who need it most. Please see example of the technology within the appendix.

This is a cloud based system produced by In Your Element Ltd, enabling healthcare professionals and employers to connect clients with chronic conditions and health risks, to quality assured community based providers of interventions across domains of physical activity, diet and nutrition and mental health. It has built in tracking, evaluation & support & quality assurance for both Healthcare Professionals and clients

- 3) **Referral to Psychological Wellbeing Practitioner as required.**

Should a participant present with very elevated scores on Anxiety, Depression, or Binge Eating, a referral to the onsite PWP will be made, whereby a short course of Low Intensity CBT will be included as part of the overall holistic intervention. The theory behind this relates to the COM-B model (Health Psychology intervention model) whereby those who, for whatever reason, cannot commit to healthy lifestyle due to psychological barriers, may need to address such barriers before the above can have a chance to work. Therefore, we intervened with the negative psychological barriers in order to support positive health behaviour change. 15 clients out of the total 52 who initially signed up at baseline were referred to the PWP during the programme.

The COM-B model has been mapped to the low intensity cognitive behavioral treatment competency scale to show key areas for consideration. The model enables treatment to take place with a consideration of the interaction between the three factors (Capability, Opportunity and Motivation) and how these underpin the behaviors which maintain the patients presenting problem (in this case depression/anxiety or binge eating are maintaining an unhealthy lifestyle leading to Diabetes Risk). The emphasis being that the practitioner applies the model to capitalize on opportunities to facilitate change. Applying the framework in this way aims to assist practitioners to deliver in session interventions or between session work, sensitively to patients.



Inclusion criteria

Those with BMI>30 and with high risk score on the Finrisc questionnaire (Diabetes Risk Measure).

Exclusion criteria

Those with an existing diagnosis of Type 2 Diabetes, and those with lower than 30 BMI were excluded from participating in the pilot.

Ethics: As this was a pilot intervention delivered in the The Old Library Trust, Health Living Centre, Derry, the current ethical application only seeks access to the retrospective data, gathered on the above time points (Week’s 1, 4, 8 and 12). The data has now been gathered and the pilot intervention has ceased. The evaluation began on end of May 2015 and ended on the end of August 2015. The raw data currently resides on the Derry Healthy Living Centre, where access to this anonymised data was requested to use as part of the current pilot study.

Sample:

The sample was recruited by staff in The Old Library Trust, Health Living Centre, Derry. Those identified with a BMI> 30 were invited to participate in the trial. The details of procedure can be seen below. The number of people recruited to the pilot trial at baseline was 56 (41 females 75%; and 10 males (17%).

		Gender			
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Female	42	75.0	80.8	80.8
	Male	10	17.9	19.2	100.0
	Total	52	92.9	100.0	
Missing	999.00	4	7.1		
Total		56	100.0		

Procedure

Recruitment and data collection procedure:

- The staff within The Old Library Trust, Health Living Centre, Derry identified individuals with a BMI over 30 through a social network advertisement and through promotion within and around the Healthy Living Centre, which announced a Diabetes risk assessment and prevention programme.
- An information evening was set up to explain the programme on offer and after gaining consent, some baseline data was gathered.
- The staff reassured participants of confidentiality of client responses and anonymity of data collected. Participants were also be informed of right to withdraw at any time, without explanation.
- The baseline assessments were weight, height, BMI, waist circumference, medical history, sleep quality, alcohol consumption, and any physical impairment, social history regarding marital status, employment, and education.
- Diabetes risk questionnaire was also issued- identifying whether participant may be Pre-Diabetic. Issue further scales on social isolation, loneliness, depression, and binge eating.
- This data was the re- collected at weeks 4, 8 and 12 (post intervention)
- Next stage involved the implementation of the intervention to the 56 participants recruited

The Interventions:

1) 'My social prescription®' (the intervention tool) consisted of the following:

- At week 1 each client was given a 'Social Prescription' via the digital My Social Prescription® tool. The 'Social Prescription' was generated by their individually assigned 'WellCare Coach'. The tool helps identify the key supports in the local area, which will specifically support life style change, across the 3 main domains of physical activity, diet/nutrition and mental health and wellbeing. The overall aim to reverse pre-diabetic high risk to low risk by reducing BMI to normal range.
- This includes identifying a range of exercise groups, whether it be walking, running, dancing, swimming, all of which will be adapted completely to each individuals likes and needs.
- In terms of diet, this will include locating cookery classes, or weight loss groups and weekly weigh in/support classes locally based to the client, or other more suitable one to one support if preferred.
- In terms of mental health and wellbeing, this will include identifying other relevant psychological therapies/counselling from the range of local charities or onsite counsellors based locally to the client.
- Follow up support will come in the form of 'telephone session', in the weeks 2 -12, to check in on client and maintain motivation.
- At 6 weeks, a further one to one session will be organised to re-assess the baseline factors.

2: 'Take Action to Prevent Diabetes' IMAGE Toolkit consisted of the following:

'The IMAGE Toolkit for diabetes prevention provides practical information for anyone involved in healthcare and prevention activities for adults at risk of developing type 2 diabetes (which will be referred to throughout as 'diabetes'). This includes those working in primary and specialised healthcare services, physicians, physical activity experts, dieticians, nurses, and also others planning or already involved in diabetes prevention interventions (e.g. teachers, business partners)'.

'The IMAGE Toolkit for diabetes prevention also provides useful information for local and national politicians and health policy makers interested in creating an environment which facilitates healthy ageing and the implementation of the WHO recommendation that "we must make the healthy choice the easy choice."'

<http://www.idf.org/sites/default/files/IMAGE%2520Toolkit.pdf>

This booklet was produced by the IMAGE Toolkit working group IN 2010:

J. Lindström, A. Neumann, K.E. Sheppard, A. Gilis-Januszewska, C.J. Greaves, U. Handke, P. Pajunen, S. Puhl, A. Pölonen, A. Rissanen, M. Roden, T. Stemper, V. Telle-Hjellset, J. Tuomilehto, D. Velickiene, P.E. Schwarz on behalf of the IMAGE Study Group. 2010

Data handling and analysis

Once both Time 1 and Time 2 data has been collected from both groups, the data will be inputted into SPSS version 21 to be prepared for analysis.

Data analysis will seek to determine the following:

- 1- Descriptive statistics, frequency statistics and cross tabulations of base line, and post 6 weeks' data.
- 2- Inferential statistics will test for statistically significant differences between Pre and Post pilot trial scores (intervention group), and compare these scores to the usual care control group.
- 3- Further secondary analysis can conduct regression analysis to test whether the other additional factors such as depression, binge eating, loneliness and social isolation and poor sleep can predict poor/negative health outcomes overall.

Once data is analysed, the study will be written up in the format of a published academic paper, targeting 'Diabetes Care' journal. Data will also be disseminated via conference proceedings etc.

Results

Changes in Type 2 Diabetes Risk Scores

Diabetes Risk Scores Comparing Baseline Week 1, with Weeks 4, 8 and 12, where week 12 was the end of the intervention.

Table 1: Representing the Diabetes Risk Mean Scores for Baseline Week 1 through to follow up Week 4, 8 and 12 using the Finrisk measure.

	N	Mean	Std. Deviation	Std. Error Mean
Diabetes Risk Baseline Week1	42	12.0952	3.07476	.47445
Diabetes Risk Score Week 4	8	10.1250	3.27054	1.15631
Diabetes Risk Score Week 8	6	9.1667	3.86868	1.57938
Diabetes Risk Score Week 12	31	9.4516	3.37480	.60613

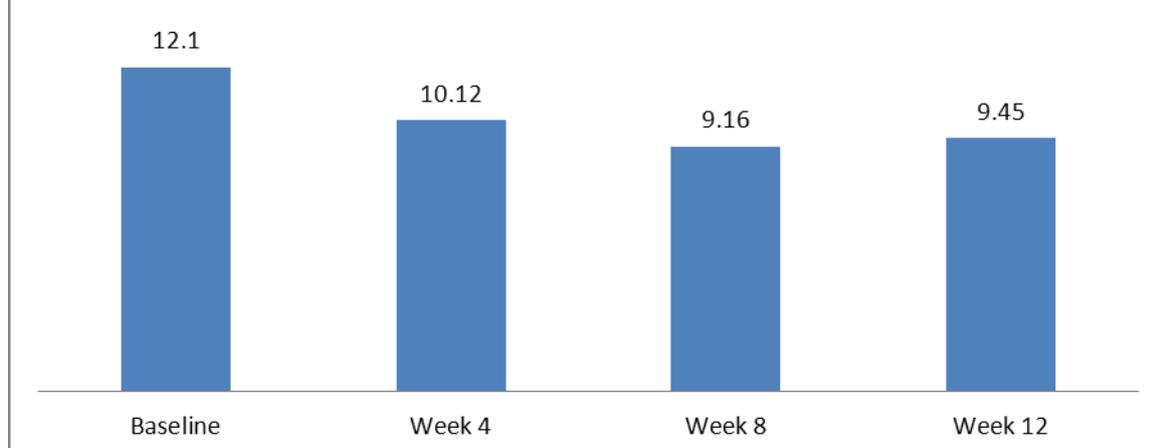
The Mean scores on Diabetes Risk have reduced from 12.095 in Week 1 Baseline to 9.4516 in Week 12 (end of intervention)

Table 2: Representing T Test Statistical Analyses across the 4 time points for Diabetes Risk Scores, indicating that there is a statistically significant difference in mean Diabetes Risk Scores between Week 1 Baseline and Week 4, 8 and 12.

	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Diabetes Risk Baseline Week1	25.493	41	.000	12.09524	11.1371	13.0534
Diabetes Risk Score Week 4	8.756	7	.000	10.12500	7.3908	12.8592
Diabetes Risk Score Week 8	5.804	5	.002	9.16667	5.1067	13.2266
Diabetes Risk Score Week 12	15.593	30	.000	9.45161	8.2137	10.6895

Note that the Mean Diabetes Risk Scores continue to decrease from 12 through to 9. However, more intervention would be needed to maintain this reduction in Diabetes risk.

Diabetes Risk Scores at Baseline (Moderate level Risk) compared to Weeks 4, 8 and 12 (now indicating low/no risk)



Diabetes Risk Indicator

Those who score indicator:

Lower than 7 – estimated 1 in 100 will develop the disease

7-11 – Slightly elevated, estimated 1 in 25 will develop the disease

12-14 - Moderate, estimated 1 in 6 will develop the disease.

15-20 – High, estimated 1 in 3 will develop the disease.

Higher than 20 – Very high, 1 in 2 will develop the disease

The results indicate that with the implementation of :

- 1) The Take Action to prevention Type 2 Diabetes toolkit along with
- 2) The Social Prescription online tool to assist clients engaging in community resources designed to assist with lifestyle change (Exercise and diet, relaxation, stress management).
- 3) Psychological Support for those who need it (using Low Intensity CBT)

The clients who entered the programme had a mean Diabetes Risk Score of 12, indicating that they were moderately at risk of developing Type 2 Diabetes. The intervention has been shown to be effective as these scores reduced from 12 (moderate risk) to 9, which indicated slightly elevated risk of developing Type 2 Diabetes.

Overall, this would suggest that the intervention has a strong efficacy and evidence base as it has reduced the risk of Type 2 Diabetes from moderate to slightly elevated for the majority who participated in the programme.

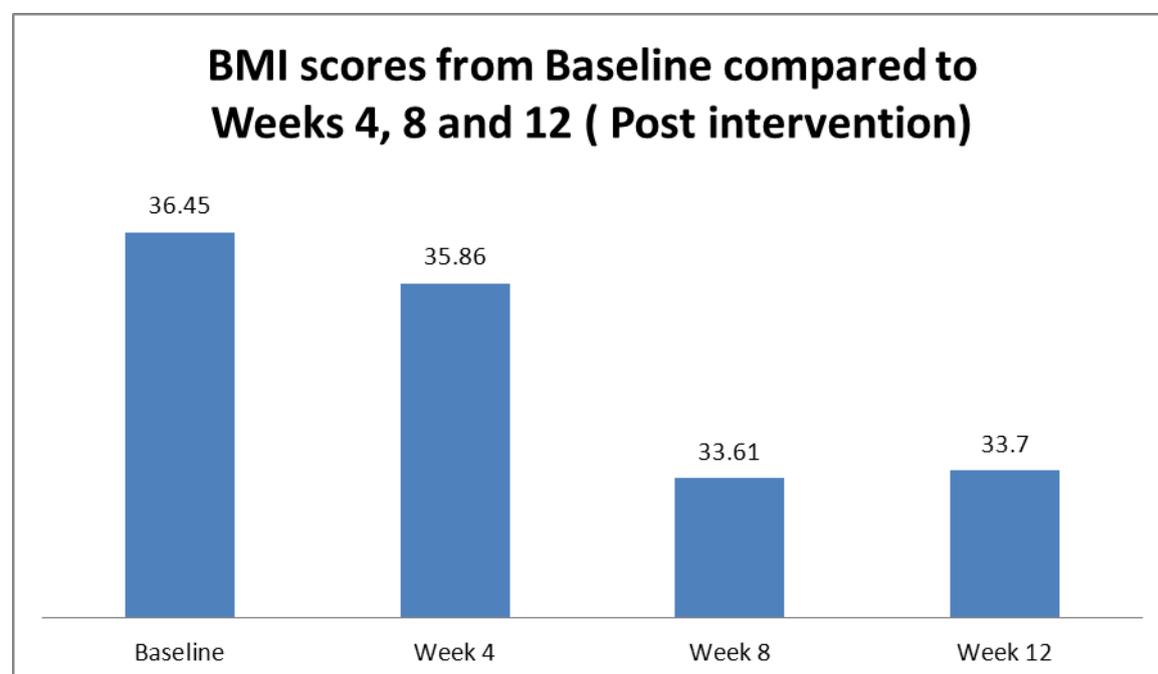
Body Mass Index (BMI) Changes

Table 3: Representing the Mean Scores for BMI at baseline, week's 4, 8 and 12 (post intervention)

	Descriptive Statistics				
	N	Min	Max	Mean	Std. Deviation
BMI Baseline	51	27.60	57.90	36.4529	6.44693
BMI Week 4	44	26.80	54.70	35.8614	6.23901
BMI Week 8	27	26.80	47.20	33.6185	5.20281
BM1 Week12	35	.00	54.10	33.7057	8.57438

Table 4: Representing the results for Repeated Measure T Test (test for significant differences between 2 time points- baseline and Week 12).

Paired Samples Correlations			Correlation	Sig.
Pair 1	BMI Baseline & BMI Week 12		.823	.000



The Bar Chart above indicated that BMI scores steadily decreased from baseline, through to Week 4, 8 and 12, where all variances observed between baseline and week 12 were statistically significant.

Waist Circumference Changes

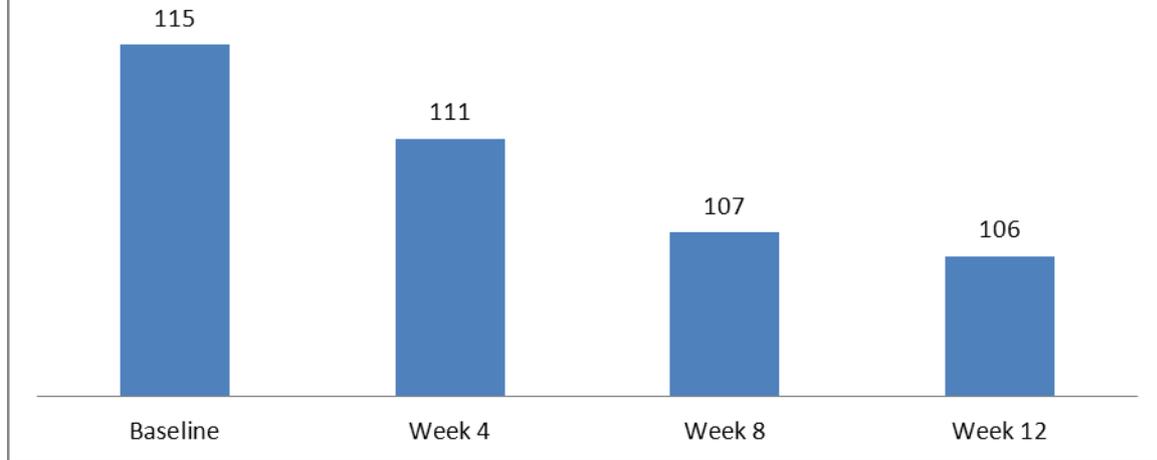
Table 3: Representing the Mean Scores for Waist Circumference at baseline, week's 4, 8 and 12 (post intervention)

	Descriptive Statistics				
	N	Min	Max	Mean	Std. Deviation
Waist size at baseline	52	3.00	151.00	115.0288	22.02325
Waist size at Week 4	46	4.00	149.00	111.4152	21.08179
Waist size at Week 8	31	89.50	137.00	107.9839	11.91182
Waist size at Week 12	39	.00	140.00	106.6667	22.13991

Table 4: Representing a Paired Samples (Repeated Measures) T test (testing for significant differences on Waist Circumference between Baseline and Week 12.

		Paired Samples Test					t	df	Correlation	Sig. (2 tailed)
		Paired Differences								
		Mean	Std. Deviation	Std. Error	95% Confidence Interval of the Difference					
					Lower	Upper				
Pair 1	Waist Size Baseline compared with Waist Size at Week 12	7.91026	5.60999	.89832	6.09171	9.72881	8.806	38	.974	.000

Waist Circumference scores at Baseline, compared to Weeks 4, 8 and 12 (Post Intervention)



The Bar Chart above indicated that Waist Circumference scores steadily decreased from baseline, through to Week 4, 8 and 12, where all variances observed between baseline and week 12 were statistically significant.

Changes in Depression Scores

Table 4: Representing the Depression Scores from Baseline Week 1 to Week 4, 8, 12. Using the standardised PHQ9 measure of Depression

	N	Minimum Score	Maximum score	Mean score	Std. Deviation
Depression Scores at Baseline	50	.00	24.00	10.0800	7.16807
Depression Scores at Week 4	48	.00	22.00	7.1042	5.76947
Depression Scores Week 8	30	.00	22.00	6.3000	6.58708
Depression Scores Week 12	38	.00	23.00	5.1316	5.68626

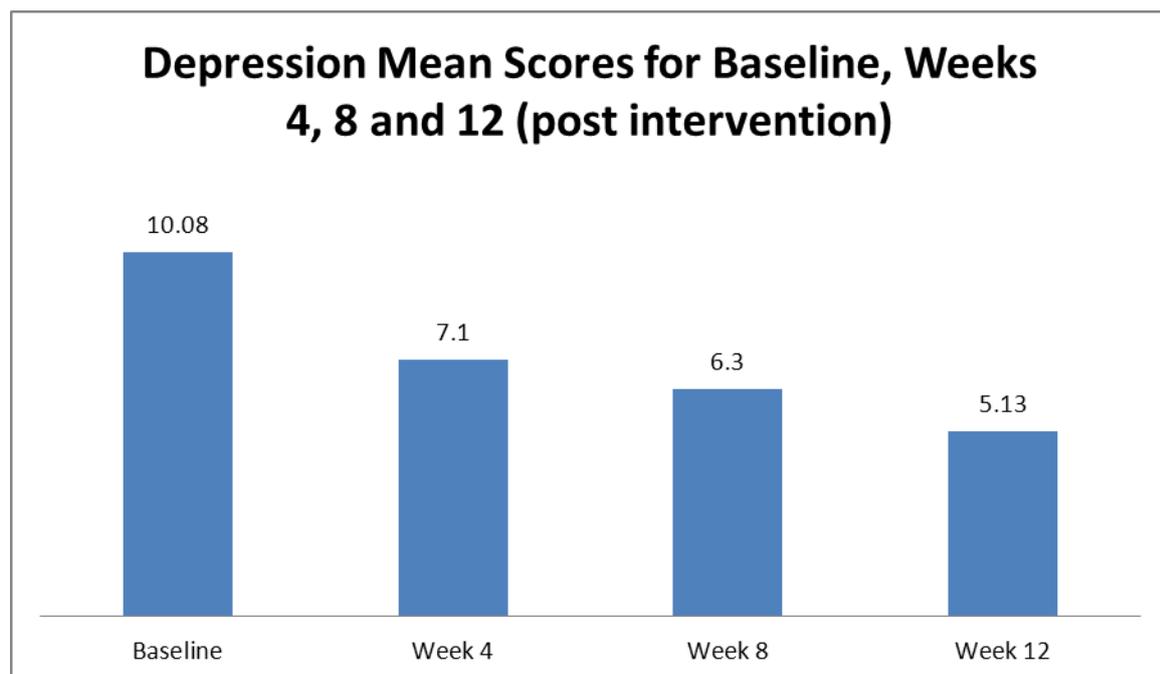
Note that the Mean scores at Baseline for Depression were 10.0800, which continue to reduce at week 4, 8, and 12. The Table below demonstrates that these observe differences are statistically significant.

Table 5: Repeated Measures T Test Between Baseline and Week 12

	Mean	N	Std. Deviation	Correlation	Sig.
Pair 1 Depression Baseline	10.0800	50	7.16807	}	.762
Depression Scores Week 12	5.1316	38	5.68626		

Table 6: Representing the Statistically significant Differences between Depression Scores at Baseline Week 1 compared to Week's 4, 8, and 12.

		Sum of		Mean		
		Squares	df	Square	F	Sig.
Depression Scores Week 4	Between Groups	1029.801	19	54.200	2.741	.009
	Within Groups	514.133	26	19.774		
	Total	1543.935	45			
Depression Scores Week 8	Between Groups	967.756	16	60.485	2.674	.045
	Within Groups	271.417	12	22.618		
	Total	1239.172	28			
Depression Scores Week 12	Between Groups	832.311	16	52.019	3.003	.011
	Within Groups	346.500	20	17.325		
	Total	1178.811	36			

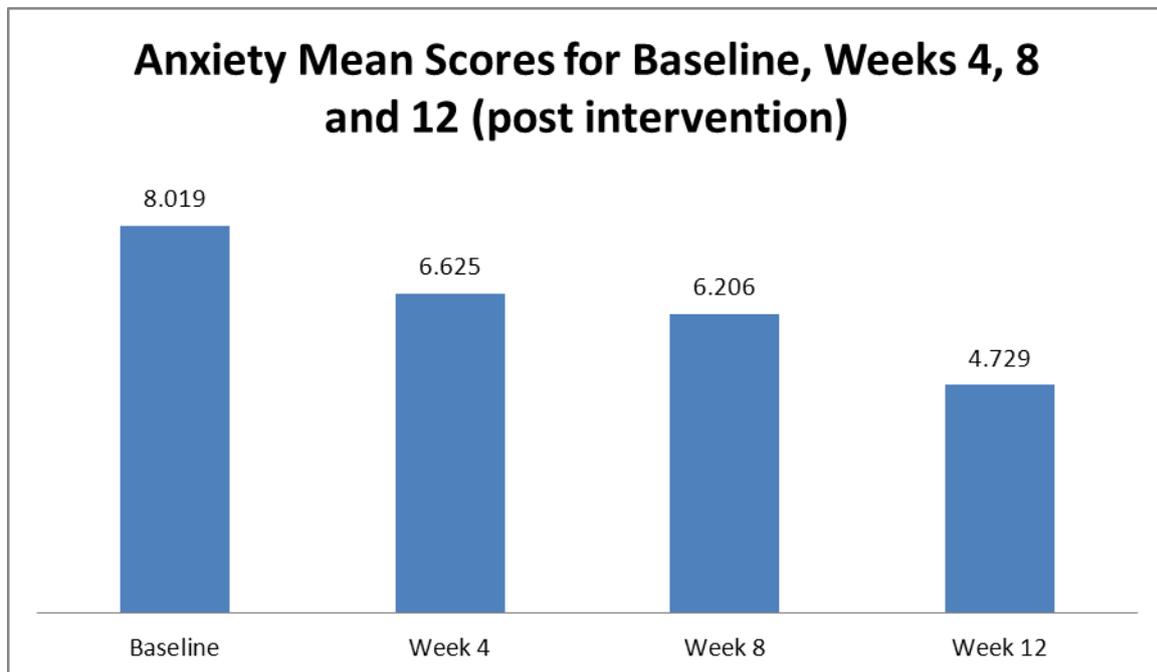


The Bar Chart above demonstrates that at Baseline, the Depression Mean scores were 10.08 and as the intervention was implemented, the Depression Scores reduced in week 4, 8 and 12. At the end of the intervention the Depression mean scores had reduced by half.

Changes in Anxiety Scores

Table 7: Representing the Anxiety Scores from Baseline Week 1 to Week 4, 8, 12. Using the standardised GAD7 measure of Anxiety

	No. of clients	Min	Max	Mean	Std. Deviation
Anxiety Mean Scores at Baseline Week 1	52	.00	21.00	8.0192	6.39083
Anxiety Mean Scores Week 4	48	.00	20.00	6.6250	5.78194
Anxiety Mean Score Week 8	29	.00	29.00	6.2069	6.77906
Anxiety Mean Scores Week 12	37	.00	17.00	4.7297	5.48558



The Bar Chart above demonstrates that at Baseline, the Anxiety Mean scores were 8 and as the intervention was implemented, the Anxiety Scores reduced in week 4, 8 and 12. At the end of the intervention the Anxiety mean scores had reduced by half.

To test whether these observed differences were statistically different, a paired samples, repeated measures, T test was carried out to analyses the differences between Baseline and Week 12.

Table 8: Paired Repeated Measures T Test showing significant differences were noted between Baseline and Week 12.

Paired Samples Correlations		
	Correlation	Sig.
Pair 1		
Anxiety Mean Scores at Baseline		
compared with	.802	.000
Anxiety Scores Week 12		

The table shows that with a Sig. of .000 that the differences in mean scores were indeed statistically different, indicating that the intervention was able to reduce Anxiety scores significantly enough by week 12 to demonstrate an evidence base for the intervention.

Changes in Binge Eating Scores

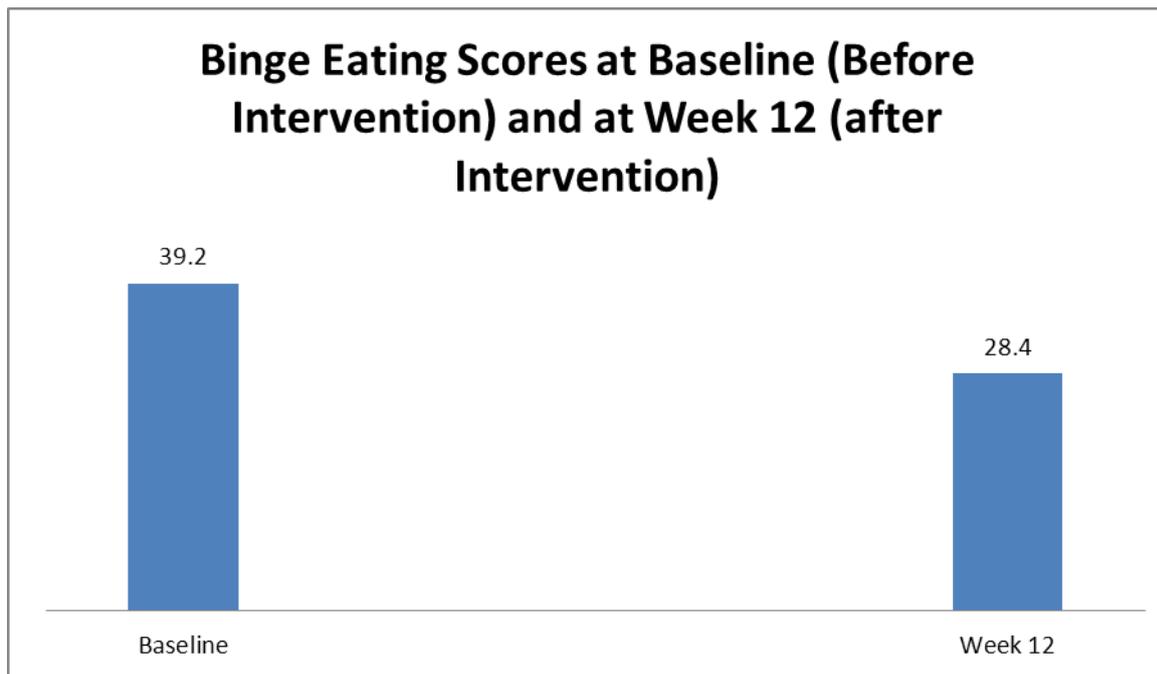
Table 9: Descriptive Statistics for Binge Eating at Baseline and Week 12 (post intervention)

	N	Min	Max	Mean	Std. Deviation
Binge Eating Baseline	45	17.00	58.00	38.7111	7.84689
Binge Eating Score Week 12 (Post Intervention)	36	18.00	52.00	28.2222	8.37039

Table 10: Representing the Binge Eating Scores from Baseline Week 1 compared to Week 12 only. Using the standardised Binge Eating Measure

		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
Pair					Lower	Upper			
1	Binge Eating Baseline compared with Binge Eating Score Week 12 (Post Intervention)	10.77	9.858	1.666	7.385	14.16	6.46	34	.000

Table 10 above indicates that the differences between baseline and week 12 on the measure of binge eating were statistically significant. See Bar chart below which demonstrates same.



Bar Chart shows that the mean scores for Binge Eating at baseline were high at 39.2, which after 12 weeks of the proposed intervention, these scores reduced to 28.4. These changes were statistically significant, as per Table 10.

A summary of the Focus Group Findings



Feedback Focus Group

My Social Prescription

What did you like?

- Great choice of exercise classes
- Having a selection of beginners exercise classes
- Regular weigh ins
- One to one support from mentor
- Confidence building from group and mentors
- Nutrition information sessions
- Meeting new people
- Text messaging from mentor

What did you not like?

- Restricted times of classes
- Not enough choice of beginners only exercise classes
- Not enough choice right across the city for exercise and nutrition sessions
- Water based exercise not included
- No walking classes to choose from
- Not enough light exercise classes more specific for those with existing health conditions
- Summer season difficult for childminding arrangements
- Would like support to continue in some form after the 12 week programme
- More support from mentors (not just through phone online support would be better)

What would you like?

- More online support
- Our own sign in to change or amend our social prescriptions
- Online chat with mentors and other attendees on the programme
- Ability to get special offers from the places offering classes
- Weekly weighs in dotted across the city
- More choice of classes
- More support from mentors but online

What's next?

- To keep going
- To keep motivated
- Keep trying new classes
- I will get there
- If i fall off the wagon I will start again

Conclusion

The current pilot set out to trial a unique Diabetes Prevention Programme (DPP), designed to reverse Diabetes risk scores within a deprived community setting in Northern Ireland.

This study provided statistical evidence to support the effectiveness of this unique DPP. This unique/bespoke Diabetes Prevention approach incorporated the COM- B theoretical model, supporting the adoption of a more personalised, tailored made, medicine approach to achieve more effective health and wellbeing outcomes pertinent to Diabetes Risk. Specifically, the study found that Diabetes Risk scores, as measured by the recognised FINRISC measure, dropped significantly at baseline from having a mean group score indicating 'moderate risk of developing Type 2 Diabetes', to a mean score which indicated 'mildly elevated risk of developing Type 2 Diabetes risk' at Week 12, which was the end of the DPP. Other significant findings indicated support for this unique DPP, as BMI, waist circumference, depression, anxiety and binge eating scores all reduced significantly between baseline measures and week 12 scores. In other works, all health and wellbeing measures improved over time, from baseline week 1 to week, 4, 8 and continued to improve in week 12, indicating positive improvement to the health and general wellbeing of those participating in the pilot.

Specifically, the noted significant differences were as a result of combining '*Take Action to Prevent Diabetes*' a well-established DPP in Europe (Lindstrom, 2010), with a novel digital tool '*My social prescription*', creating a more personalised medicine approach. At the same time, the trial identified and simultaneously treated incidental depression, anxiety, or binge eating problems in (N- 15) participants who had particularly high scores in either depression, anxiety or binge eating. This added feature of the programme was included as it has been well established that these factors can act as barriers to effective and long term health behaviour change. Hence the need to include psychological interventions as and when required. The treatment approach for psychological issues adopted a Low Intensity CBT delivered by a Psychological Wellbeing Practitioner, alongside the '*Take Action to Prevent Diabetes*' program and the personalised digital tool '*My social prescription*'.

Overall, this novel, three arm DPP, is unique to other established DPP'S in Europe, Ireland, NI and UK as the existing DPP'S have not included personalised approaches in the form of online platforms (i.e. social prescribing), nor have they attempted to intervene with potential psychological barriers such as depression, anxiety or binge eating disorders; factors known to decrease motivation for long term health behaviour change. Therefore, the pilot has demonstrated significant efficacy for reversing Type 2 Diabetes risk using the Finrisc measure in the first instance, and has indicated some evidence base to start with, and develop further.

Limitations and future recommendations

The study data recognised that there were some notable dropout rates at mainly week's 4 or 8. However most participants came back at week 12 to complete the programme. Therefore, motivation assessments may be needed around this time.

Whilst the FINRISC measure is well established in identifying people at risk of Diabetes, it is not a diagnosable tool. To diagnose Diabetes risk from a medical standpoint, an oral glucose tolerance blood test would be required to diagnosed 'Impaired Glucose Tolerance', i.e. Pre-Diabetes.

Furthermore, whilst the Diabetes risks scores reduced, there may be still more work to be done to ensure that BMI scores reduce to below 30, indicating that the intervention duration may need to be increased.

Aside from BMI scores, in order to ensure long term changes and longitudinal reduction in Diabetes risk, ongoing monitoring will be required, and potentially some booster sessions to maintain diabetes risk reduction. Other similar studies in the UK would have followed up at 3, 6, 9, 12 and 24 months (Lets Prevent Diabetes, Yates et al. 2014) to ensure that the DPP had a lasting effect. We are recommending that 'my social prescription' could be quite effective in maintaining long term benefits as it includes personalised social support, including a range of options/choices for the participant in their local areas, making maintenance potentially more independent and realistic. My social prescription, introduced within this DPP, can continue long after the withdrawal of the health professional. Thus, long term positive change may be observed without the ongoing active support of a health care professional, thereby reducing health care costs in several ways.

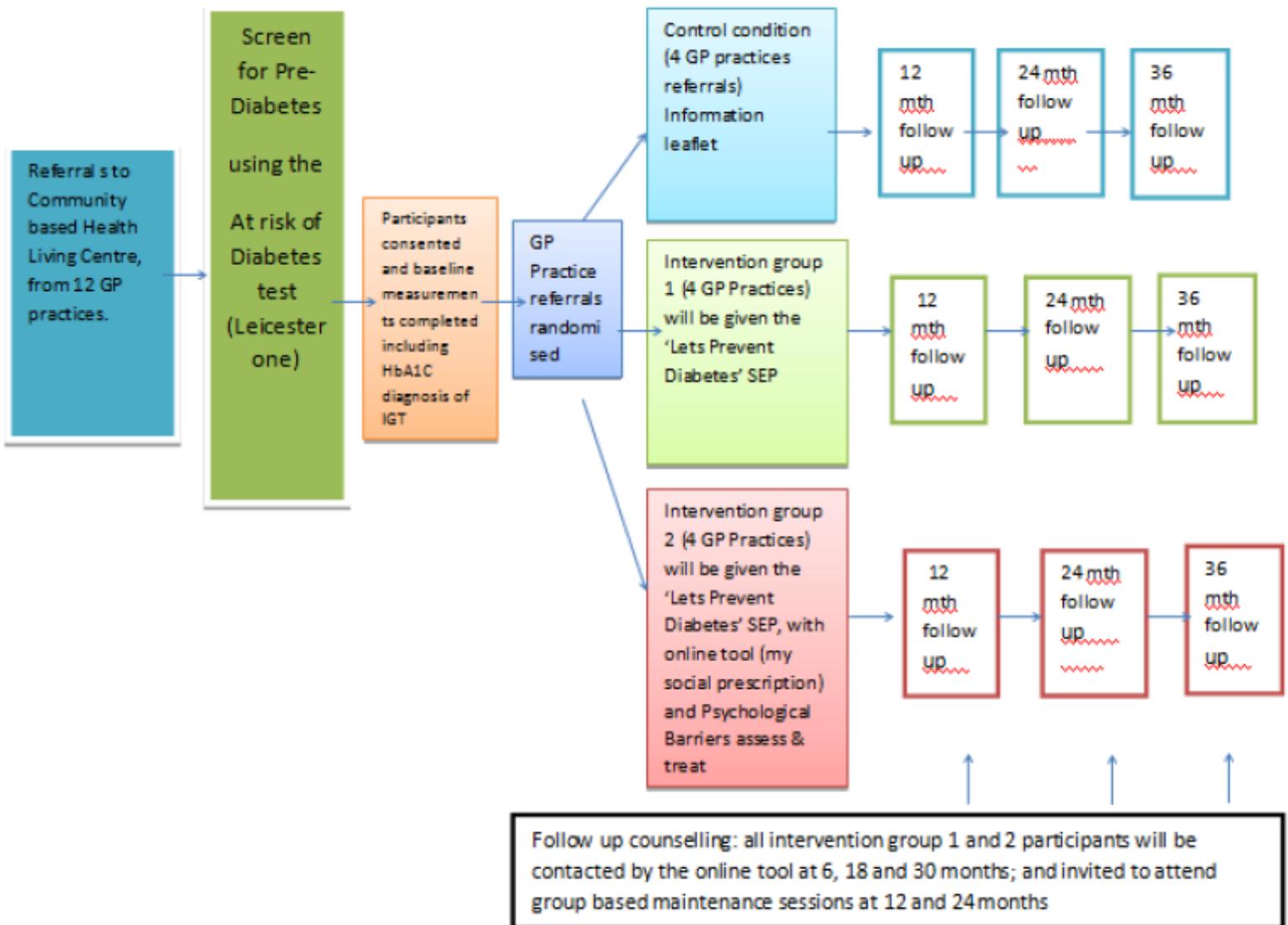
In order to test this, a Cluster RCT , incorporating three arm design, where the active intervention phase is extended to 18 weeks, with ongoing monitoring, follow up and booster sessions included for up to 12/18 months is recommended; a recommendation which will require significant research grant funding.

See below a Cluster RCT which could be taken to the next stage, should the appropriate level of funding be resourced.

Method of New RCT

The current new Cluster RCT aims to adapt the method above, recruit the sample via the GP practices, but will implement the DPP 'Let Prevent Diabetes', in a community setting (Health Living Centre). Within this new method, there will be three arms to the RCT, instead of two, which was in Yates et al (2012).

See below new cluster RCT Design for a DPP which includes ‘My Social Prescription’, Lets Prevent Diabetes programme, and psychological support



Measured and Intended Outcomes:

- Reduced Pre-Diabetes risk score
- Reduced HbA1C score to normal range
- Reduced weight/BMI
- Increased behaviour activation
- Increased daily exercise: Acti- graph measurements
- Increased mood and well being
- Decrease in binge eating scores