STUDY REPORT

Interim Evaluation of Let's Get Active Programme 2017/2018

Development Phase:	NHS Service Evaluation
Investigational Products:	12-Week Education and Exercise Programme
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GLOSSARY OF TERMS AND ABBREVIATIONS

BMI	body mass index
CCG	Clinical Commissioning Group
GP	general practitioner
HbA1c	glycosylated haemoglobin
HRA	Health Research Authority
LGA	Let's Get Active
NHS	National Health Service
PHQ-9	patient health questionnaire 9
QALY	quality adjusted life year
SD	standard deviation
T2DM	type II diabetes mellitus

1 SUMMARY

Aims: To evaluate the effect of a 12-week education and exercise program on HbA1c, blood pressure and quality of life in patients diagnosed with Type 2 diabetes, or who were obese or deemed at risk of developing diabetes in the future.

Introduction: The health of people in Oldham is generally worse than the England average. Local priorities include supporting people to take more control over their lives, increasing levels of community engagement and so reducing levels of behaviour that are a risk to good health. Oldham CCG commissioned "Outta Skool", a local community social enterprise, to deliver the Let's Get Active program to work with people who were diagnosed with Type 2 diabetes, who were obese or deemed at risk of developing diabetes in the future. The project was funded by Dragons' Den monies and originally targeted hard-to-engage-with minority communities in Westwood, Coldhurst and Chadderton to encourage uptake of daily exercise and healthier living. The 2017/18 programme was extended to also cover Fitton Hill, Hathershaw and Werneth.

Method: Over the first 2 to 3 weeks, patients were given intensive support to motivate and introduce them to fitness classes, healthy cooking and nutrition and food hygiene workshops. Patients were required to attend 3 exercise sessions per week.

100 patients were enrolled into the program between September 2017 and April 2018. Data collected included:

- Gender
- Age
- Height, weight and BMI
- HbA1c
- Systolic and diastolic blood pressure
- PHQ-9 scores
- Patient satisfaction survey

Supporting the Delivery of Outcomes:

CCG improvement and assessment framework 2016/17: Theme area: Better Health Diabetes

- 103a: The percentage of diabetes patients that have achieved all 3 of the NICE-recommended treatment targets
- 103b: People with Diabetes diagnosed less than a year who attend a structured education course

Oldham Council Corporate Plan 2015: Objective 2: Confident Communities – Healthy Communities.

Results

100 patients participated between September 2017 and April 2018; 87 females and 13 males met the eligibility criteria of patients at least 18 years old who had type II diabetes mellitus, were obese or were deemed at risk of type II diabetes mellitus.

The average age was 49 years and ranged from 32 to 75 years. The majority of patients were South Asian (85%) or White (10%). 7 patients were current smokers.

Objective Measures: Patients on the 12-week programme experienced, on average, a 4.4 mmol/mol reduction in HbA1c, a 5.2 mmHg reduction in systolic blood pressure and a 3.5 mmHg reduction in diastolic blood pressure. On average, patients lost 2 kg and reduced their BMI by 0.8 kg/m^2. The number of patients with HbA1c >58 mmol/mol was reduced by 7 patients and the number of patients with blood pressure >140/80 mmHg was reduced by 16 patients from Week 0 to Week 12.

QRISK reduction in the cardiovascular event in the next 10 years was -0.84 in the overall population and was statistically significant ($p<0.001$); the reduction was -1.34 in the male population and -0.67 in the female population. For the group as a whole, the mean percentage reduction was 5.6%. For females the mean percentage reduction was 6.1% and for males it was a 4.4% reduction

Subjective Measures: There was a very strong trend away from clinically depressed PHQ-9 scores. Overall, 73 of the 100 participants started with a PHQ-9 score of ≥10 but had reduced this figure to <9 by Week 12. By Week 12, no patients were severely depressed (reduced from 20) and the majority of patients had no/minimal depressive symptoms (39 patients) or had mild depressive symptoms (43 patients). Over the course of the study, depressive symptoms were resolved in 36 patients. The average reduction in PHQ-9 score was by 5.0 points from Week 0 to Week 6 and by 9.6 points from Week 0 to Week 12; both of these reductions were statistically significant ($p<0.001$).

The program was delivered with minimal wait and resulted in 78% of patients saying that they felt more in control of their health. All patients adopted at least one healthy lifestyle attribute (the average was four). Patient satisfaction was high with overwhelmingly positive feedback, and 100% of patients found staff friendly and saw the benefit of attending.

A video about the programme is available at https://youtu.be/NACjPT7ZT5A

Cost Effectiveness: The cost of running the programme in 2017/18 for an anticipated 200 patients is £80,000 (£400 per user). Of this, £24,000 is venue hire paid to Oldham Council. The number of participants was limited by obtaining HbA1c results through GP surgeries. A scheme for measuring HbA1c at home is being considered, which would allow for approximately twice as many patients to enter the scheme. If the above limitations were removed, the future cost per patient could be expected to be £140 per patient.
Results from the LGA 12-week programme show an overall 5.6% relative risk reduction of cardiovascular events using QRISK. A cardiovascular event costs the NHS an average of £2400 (Ward, 2005). Therefore, the programme can be expected to save the NHS approximately £14,400 over the next ten years for each 100 participants. Taking social value into account, the mean QALYs preserved per cardiovascular event avoided are 0.7934 per patient, or £15,808 per patient (based on a QALY having a value of £20k).
Further, a 1% reduction in HbA1c in type 2 diabetic patients has a predicted gain of 0.413 QALYs (McEwan, 2010). The present study showed a reduction of 7.8%, representing 3.2 QALYs and £64K saving per type 2 diabetic patient.
The improvement of depression symptoms described above is also anticipated to reduce social and medical costs in patients who participate in the programme. The programme is therefore an extremely effective use of resources.

Sustainability:

Of 50 patients followed up from their participation in the LGA programme in 2015/16, data were available for 45 patients. The average continued weight loss to April 2018 was 2.26 kg, with 42 patients losing further weight and 3 patients staying the weight they were at Week 12. The results from the programme are therefore highly sustainable.

Discussion:

The LGA programme met its objectives. Namely, there were:

- Reductions in the number of patients with HbA1c ≥50 mmol/mol (from 27 patients at Week 0 to 20 patients at Week 12)
- Reductions in the number of patients with blood pressure ≥140/80 mmHg (from 26 patients at Week 0 to 10 patients at Week 12)
- Delivery of a structured education course for people with diabetes diagnosed for less than a year

The LGA programme has shown remarkable improvements across all areas measured. There was a very strong trend away from clinically depressed PHQ-9 scores. The program was delivered with minimal wait and the effect of the program is sustainable.

In terms of funding compared to other weight loss schemes, without the physical exercise component Weight Watchers schemes already cost in excess of £300 per person. The current programme as it stands therefore adds considerable value over existing schemes and represents considerable long-term cost savings in terms of use of health services; it also has the potential to be refined to an even more cost-efficient programme.

The LGA program is an example of real community engagement in populations that have been difficult to access. The programme represents effective value for money by initiating a change of habits throughout patient communities; improving mental and physical health; and making use of council owned buildings and reducing the reliance on health care services. The extraordinary improvement in mental health shown from this programme indicates the programme's success in reaching out to previously hard-to-engage-with communities, who now feel heard and supported. Additional benefits of the programme include:

Engagement and Empowerment (Confident Communities)

- Enhanced communications, engagement and trust with the population
- Enhanced engagement with GP practices
- Empowered people to take responsibility for their own health
- Enhanced engagement with BME/Hard to reach/Women/Men
- Reduced social isolation, and opportunity to meet and make friends
- Enhanced social value
- Social and personal development
- Listening to communities and delivering services to meet their needs

Physical Health Improvements

- Knowledge of healthy eating and practical lessons to take back into the home and family
- Knowledge on diabetes prevention and management
- Weight loss
- Reduction in blood pressure
- Introduction to regular exercise
- Support for patients to sustain their health improvements and cope with long term conditions

Mental Health Improvements

- Drastically improved mental health and positive mental attitude
- Enhanced quality of life
- Reduction in stress

Employment Opportunities

- Employ 4 staff and 18 sessional staff from local community
- Aid volunteering
- Aid getting people back into work
- Certificate in food hygiene

Cost Saving Benefits

- Better management of long term conditions
- Reduced reliance on services
- Introducing use of community buildings and building the communities to use them

2 ETHICS

The Health Research Authority (HRA) was consulted to determine whether or not the project would be considered research (i.e., require ethical approval). The HRA confirmed that the project was not of the type that would constitute research.

3 INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

The Accountable Officer was John Patterson Chief Clinical Officer, Oldham Clinical Commissioning Group (CCG) Ellen House, Waddington Street, Oldham OL9 6EE, Telephone 0161 622 6500.

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This report was prepared on behalf of TRUSTECH by Remo, Southampton, SO14 3FJ.

All patient data was collected and laboratory results obtained by the patients' GP practices.

4 STUDY OUTLINE

4.1 Programme Background

Throughout 2014/15 and 2015/16, Oldham CCG commissioned "Outta Skool", a local community social enterprise, to deliver the Let's Get Active (LGA) programme to work with people who had been diagnosed with Type 2 diabetes mellitus (T2DM), who were obese or deemed at risk of developing diabetes in the future. The project, funded by Dragons' Den monies, targeted hard-to-engage minority communities in Westwood, Coldhurst and Chadderton to encourage the uptake of daily exercise and healthier living.

Two hundred individuals, referred by GP practices, received a 12-week programme supported by a personal trainer and mentor to set individual goals and targets. Over the first 2 to 3 weeks, patients were given intensive support to motivate and introduce them to fitness classes, healthy cooking and nutrition and food hygiene workshops.

Analysis of the 2014/15 data showed promising results: a 9.5% clinically significant reduction in relative risk in patients completing the lifestyle programme and a significant impact on their health and well-being.

In 2017/18, the CCG in partnership with TRUSTECH, the North West of England Innovation Service, agreed that the LGA lifestyle programme would be subject to the rigour undertaken on the NHS Oldham CCG Dragons' Den 3 Innovation Evaluation Programme.

This report details analysis of the first 100 patients to complete the 2017/18 programme, and a follow-up of 50 patients from the 2015/16 programme.

4.2 Study Rationale

The health of people in Oldham is generally worse than the England average. The study was intended to support people to take more control over their lives, increase levels of community engagement and so reduce levels of behaviours that are a risk to good health.

4.3 Benefit-Risk and Hazard Evaluation

No potential risks to participants were identified.

5 STUDY OBJECTIVES

5.1 Supporting Delivery of Outcomes

The strategic aims of Oldham CCG are to improve the health of the people of Oldham, to improve the care they receive and their experience of it, and to deliver the best value for money by using resources effectively.

The aim of the LGA programme was to enhance and support the quality of life for people with long-term conditions, ensuring people felt supported to manage their condition and reduce time spent in hospital (NHS Outcomes Framework Domain 2)

CCG improvement and assessment framework 2016/17: Theme area: Better Health Diabetes

- 103a: The percentage of diabetes patients that have achieved all 3 of the NICE-recommended treatment targets
- 103b: People with Diabetes diagnosed less than a year who attend a structured education course

Oldham Council Corporate Plan 2015: Objective 2: Confident Communities – Healthy Communities.

5.2 Study Objectives

In line with the CCG improvement and assessment framework, the objectives of the study were:

- To improve the percentage of diabetes patients who achieved 2 of the 3 NICE-recommended treatment targets:
    - HbA1c ≤ 58 mmol/mol (7.5%)
    - Blood pressure ≤ 140/80 mmHg (103a)
    - To have people with diabetes diagnosed for less than a year to attend a structured education course (103b).
- To deliver the LGA programme to work with people who had been diagnosed with T2DM, who were obese or deemed to be at risk of developing diabetes in the future.

6 INVESTIGATIONAL PLAN

6.1 Method

The 2017/18 LGA team re-established the programme in the areas it had previously been conducted (Westwood, Coldhurst and Chadderton); the programme was also established at Fitton Hill, Hathershaw and Werneth.

This was an open study conducted through the GP practices listed in the data summary in Appendix 4.

Individuals who had T2DM, were obese or deemed to be at risk of diabetes were referred by GP practices using a referral form. Referred patients received a 12-week programme supported by a Personal Instructor and Mentor to set individual goals and targets. Over the first 2 to 3 weeks patients were given intensive support to motivate and introduce them to fitness classes, healthy cooking and nutrition and food hygiene workshops. Sample programmes are provided in Appendix 1. Patients attended 3 workshops (introduction to diabetes workshop, nutrition workshop and healthy cooking workshop), and were required to attend 3 exercise sessions per week. Patients were organised into groups of 17 for ease of administration of the programme.

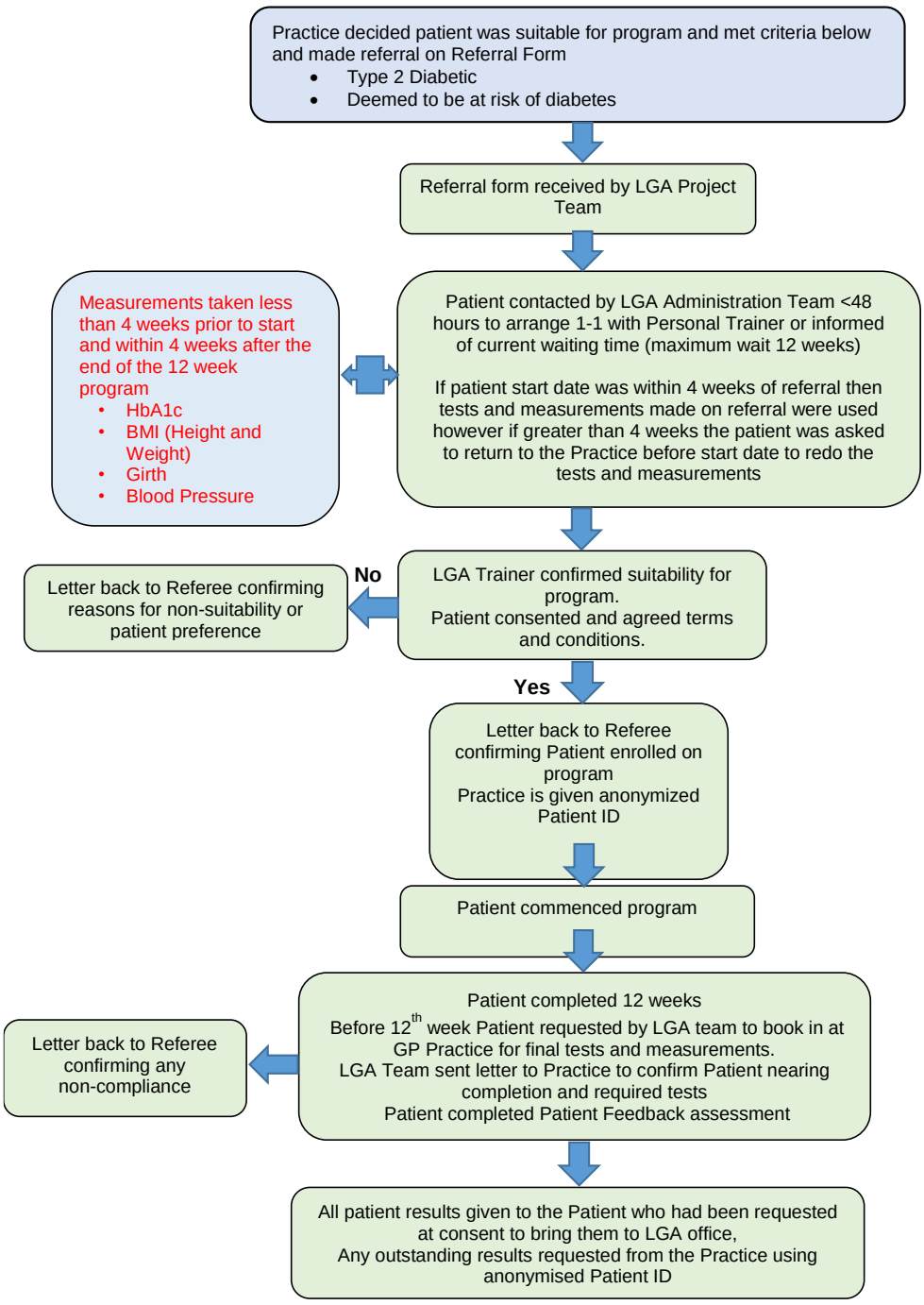
6.2 Inclusion and Exclusion criteria

Inclusion: patients were to have T2DM, be obese or be deemed at risk of diabetes.

Exclusion: patients under the age of 18 years or patients involved in any other diabetes related evaluation or study.

6.3 Study Flowchart

An overview of the study design is provided below:



6.4 Discussion of Study Design

The study followed the framework of the 2015/16 programme. The study was to recruit up to 340 patients over the 12-month funding period; 100 patients were required for the interim evaluation for this report.

7 STUDY ASSESSMENTS

7.1 Assessments

7.1.1 Physical Assessments

The following were recorded by the patient's GP practice within 4 weeks prior to the start of the 12-week programme and within 4 weeks of the end of the 12-week programme:

- Gender
- Age
- Height (cm)
- Weight (kg)
- Body Mass Index (BMI - kg/m^2)
- HbA1c (mmol/mol)
- Abdominal Girth Measurement (cm)
- Systolic and diastolic blood pressure (mmHg)

Daily activity, targets, weight and blood pressure were captured throughout the programme in a diary record (see Appendix 1 for a sample diary). At the end of Week 12 patients were encouraged to continue those activities at a subsidised charge, and were encouraged to join local providers.

7.1.2 Quality of Life

Quality of life was measured using the PHQ-9 patient health questionnaire at Weeks 0, 6 and 12:

Questions:

Over the last two weeks, how often have you been bothered by any of the following problems?

1. Little interest or pleasure in doing things?
2. Feeling down, depressed, or hopeless?
3. Trouble falling or staying asleep, or sleeping too much?
4. Feeling tired or having little energy?
5. Poor appetite or overeating?
6. Feeling bad about yourself - or that you are a failure, or have let yourself or your family down?
7. Trouble concentrating on things, such as reading the newspaper or watching television?
8. Moving or speaking so slowly that other people could have noticed?
9. Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual?
10. Thoughts that you would be better off dead, or of hurting yourself in some way?

Answers:

- Not at all = 0
- Several days = 1
- More than half the days = 2
- Nearly every day = 3

A service quality questionnaire was also used (see Appendix 2).

7.2 Quality Assurance

All data was anonymised and provided monthly to the TRUSTECH project manager from the LGA team for audit purposes. If any anomalies were identified within the data, the Principal Investigator was tasked to investigate and provide resolution within 7 working days.

7.3 Statistical Methods

Patients were measured at 3 timepoints:

- Pre-program (baseline)
- Half way through the program at 6 weeks – Selected outcomes only
- End of program at 12 weeks

The analyses focussed on changes in outcomes from baseline to each of the subsequent timepoints at 6 and 12 weeks. All outcomes were continuous in nature, and an examination of the data suggested that the changes in outcomes between timepoints were all approximately normally distributed. As a result, the paired t-test was used for all analyses.

7.3.1 HbA1c

Following recommendations from the original evaluation, HbA1c was measured and Baxter et al (2016) provides a framework to represent the HbA1c reductions by the LGA team as a financial saving over time.

7.3.2 Blood Pressure

Results were analysed using a paired t-test as described above.

7.3.3 QRISK

All data were evaluated using the QRISK tool which provides a validated tool to assess the impact on cardiovascular risk. It also provided a methodology to assess the financial impact for Oldham CCG.

7.3.4 BMI

Results were analysed using a paired t-test as described above.

7.3.5 PHQ-9 scores

The total PHQ-9 score out of a possible 27 was calculated. The score is indicative of the level of depression. A score of 10 or above is considered clinically significant symptoms of depression:

Score	Level of Depression
0-4	None-minimal
5-9	Mild
10-14	Moderate
15-19	Moderately severe
20-27	Severe

PHQ-9 data were paired samples and expected to be normally distributed.

7.3.6 Sample size

Data from the original evaluation suggested a mean BMI reduction of around 0.9 kg/m^2 (SD 0.9 kg/m^2). To support the present study to detect a similar sized difference with a 5% significance level and 90% power, 13 patients were required. To detect a smaller effect of 0.5 kg/m^2 difference, 37 patients were required.

Data from the previous evaluation suggested a mean HbA1c reduction of 10.6 units (standard deviation [SD] 10.8 units). To support the present study to detect a similar sized effect with 5% significance and 90% power, 13 patients were needed. To detect a smaller effect of 5 units difference, 51 patients were required.

7.4 Changes in the Conduct of the Study Including Changes to the Planned Analyses

Girth was not measured for most patients and was therefore not analysed for the patient population: the LGA team required Practices to measure girth, but the Practices did not do this due to time constraints; the LGA team were predominantly male and therefore did not feel that it was culturally appropriate for the LGA team to measure patients' girth.

8 RESULTS

8.1 Data Sets Analysed

This report details analysis of the first 100 patients who participated in the programme from 03 July 2017 (first patient contacted) to 29 April 2018 (last patient ended). A total of 146 patients were referred to the program during this time; the remaining 46 patients were unwilling to participate or were considered unsuitable due to health conditions. Data are provided in Appendix 3 and analysis reports are provided in Appendix 4.

The majority of patients (75%) were female; age ranged from 32 to 75 years, with an average age of 49 years. The majority of patients were South Asian (85%) or White (10%). 7 patients were current smokers.

Primary reasons for referral to the LGA programme were most frequently being overweight (69 patients) or having high blood pressure (63 patients). Other reasons were T2DM (32 patients), depression (16 patients) and other (10 patients). Patients could be referred for more than one reason.

A weighted averages calculation showed that the average patient enrolled had 2.13 comorbidities. The number of comorbidities per subject is shown in Table 1.

Table 1: Number of Comorbidities per Patient

Comorbidities	Number of Patients
0	2
1	11
2	56
3	31
Total	100

The most frequent comorbidities were diabetes (65 patients) and high blood pressure (25 patients). Other comorbidities were arthritis (4 patients), asthma (3 patients), angina (3 patients), chronic lung disease (2 patients), stroke or transient ischemic attack (1 patient) and post-traumatic stress disorder (1 patient). No patients had comorbidities of epilepsy, heart attack, atrial fibrillation, cancer, or chronic kidney disease.

8.2 Results

8.2.1 HbA1c

Data were not available for 3 patients. Out of the 97 evaluable patients, the number of patients with HbA1c over 58 mmol/mol reduced from 27 patients at Week 0 to 20 patients at Week 12.

Patients reduced their HbA1c by an average of 4.4 mmol/mol from Week 0 to Week 12, which was statistically significant ($p<0.001$). Of the 97 evaluable patients, 54 patients decreased their HbA1c, 8 patients did not change their HbA1c and 35 patients increased their HbA1c.

8.2.2 Blood Pressure

The number of patients with blood pressure over 140/80 mmHg reduced from 26 patients at Week 0 to 10 patients at Week 12.

Of the 100 patients evaluated, 79 patients showed an improvement in at least one of their systolic or diastolic blood pressures. The number of patients with an increase, decrease and no change in blood pressure are shown in Table 2.

Table 2: Blood Pressure: Number of Patients Decreasing, Increasing or with No Change

	Systolic Blood Pressure n	Diastolic Blood Pressure n
Decrease	65	65
Increase	29	32
No change	6	2
Total	100	100

n = number of patients.

On average, patients reduced their systolic blood pressure by 5.2 mmHg and diastolic blood pressure by 3.5 mmHg from Week 0 to Week 12, as shown in Table 3. Reductions in blood pressure at Week 6 and Week 12 were all statistically significant, and the mean change from baseline improved further from Week 6 to Week 12.

Table 3: Blood Pressure: Change from Baseline to Week 6 and Week 12

Outcome	n	Baseline Mean ± SD	Week 6 or Week 12 Mean ± SD	Change Mean (95% CI)	P-value
Baseline to Week 6					
Systolic BP (mmHg)	100	122.5 ± 13.7	119.1 ± 11.7	-3.4 (-5.5, -1.4)	**0.001**
Diastolic BP (mmHg)	100	75.5 ± 9.2	73.6 ± 9.1	-1.9 (-3.7, -0.2)	**0.03**
Baseline to Week 12					
Systolic BP (mmHg)	100	122.5 ± 13.7	117.3 ± 11.6	-5.2 (-7.6, -2.7)	**<0.001**
Diastolic BP (mmHg)	100	75.5 ± 9.2	72.0 ± 10.2	-3.5 (-5.5, -1.5)	**<0.001**

8.2.3 QRISK

On average, patients had a QRISK score of 12.38 at Week 0 and 11.54 at Week 12, representing an average reduction of 0.84. The overall risk reduction in the cardiovascular event in the next 10 years was -0.84 in the overall population and was a statistically significant decrease ($p<0.001$). The risk reduction was -1.34 in the male population and -0.67 in the female population (Figure 1).

For the group as a whole, the mean percentage reduction was 5.6%. For females the mean percentage reduction was 6.1% and for males it was a 4.4% reduction (Figure 2).

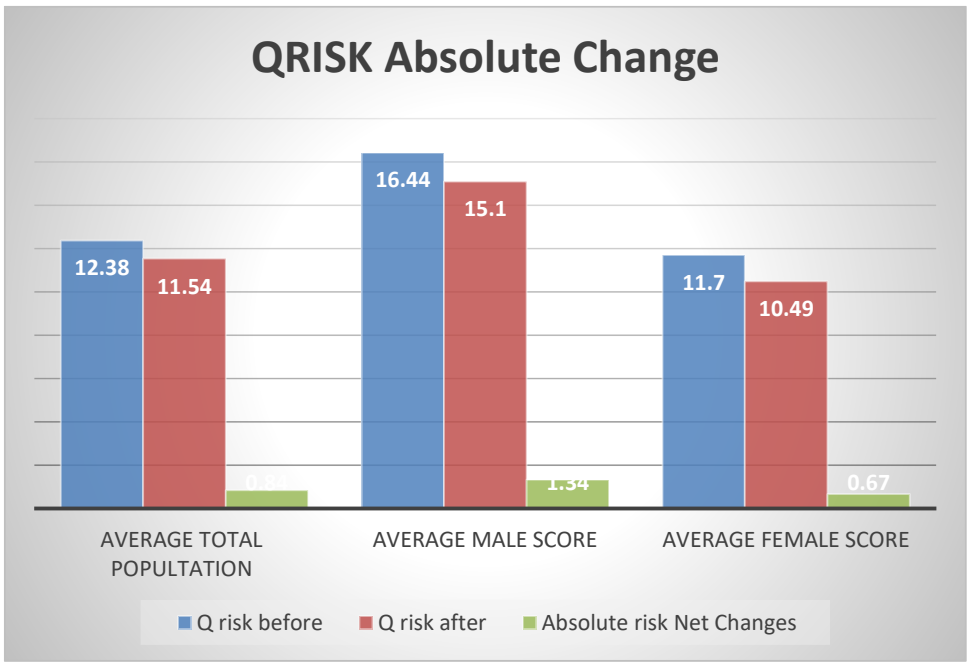


Figure 1: QRISK Absolute Change

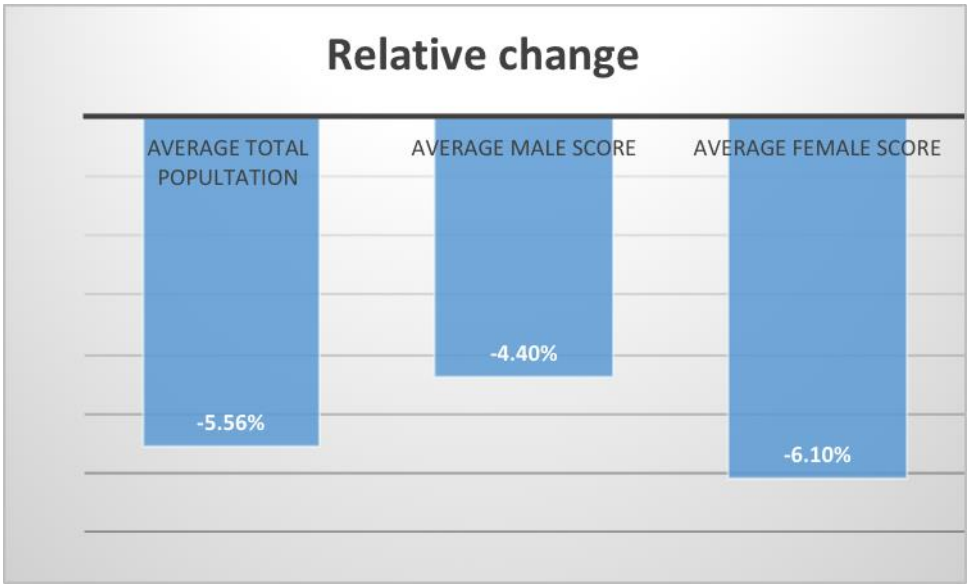


Figure 2: QRISK Relative Risk Net Changes

8.2.4 BMI

The average reduction in BMI was 0.8 kg/m^2 at Week 12, which was statistically significant ($p<0.001$). Patients lost an average of 2 kg during the programme. The number of patients who decreased, increased or had no change in BMI and weight at Week 12 of the programme are shown in Table 4.

Table 4: BMI and Weight: Number of Patients Decreasing, Increasing or with No Change

	BMI n	Weight n
Decrease	87	89
Increase	8	8
No change	5	3
Total	100	100

n = number of patients.

8.2.5 PHQ-9 scores

The PHQ-9 score was measured at Weeks 0, 6 and 12. The average reduction in PHQ-9 score was by 5.0 points from Week 0 to Week 6 and by 9.6 points from Week 0 to Week 12; both of these reductions were statistically significant (p<0.001) (Table 5). There was continued improvement in PHQ-9 score from Week 6 to Week 12.

Table 5: PHQ-9: Change from Baseline to Week 6 and Week 12

Outcome	n	Baseline Mean ± SD	Week 6 or Week 12 Mean ± SD	Change Mean (95% CI)	P-value
Baseline to Week 6					
PHQ-9 score	100	15.6 ± 4.5	10.7 ± 2.5	-5.0 (-5.4, -4.5)	**<0.001**
Baseline to Week 12					
PHQ-9 score	100	15.6 ± 4.5	6.0 ± 3.6	-9.6 (-10.5, -8.7)	**<0.001**

Table 6 and Figure 3 provides a summary of the scores, and show a trend away from clinically depressed scores (clinical depression is defined as a score of ≥10).Notably, at Week 0, 20 patients had a score indicative of severe depression and 46 patients had a score indicative of moderately severe depression, whereas by Week 12 no patients had a severe score and only 2 patients had a moderately severe score. It is also notable that by Week 12, 39 patients reported no or minimal depressive symptoms, compared to 3 patients at Week 0.

Table 6: PHQ-9 Scores at Week 0, 6 and 12

PHQ-9 Level	Week of Programme		
	Week 0	Week 6	Week 12
None – minimal	3	6	39
Mild	6	25	43
Moderate	25	57	16
Moderately severe	46	12	2
Severe	20	0	0

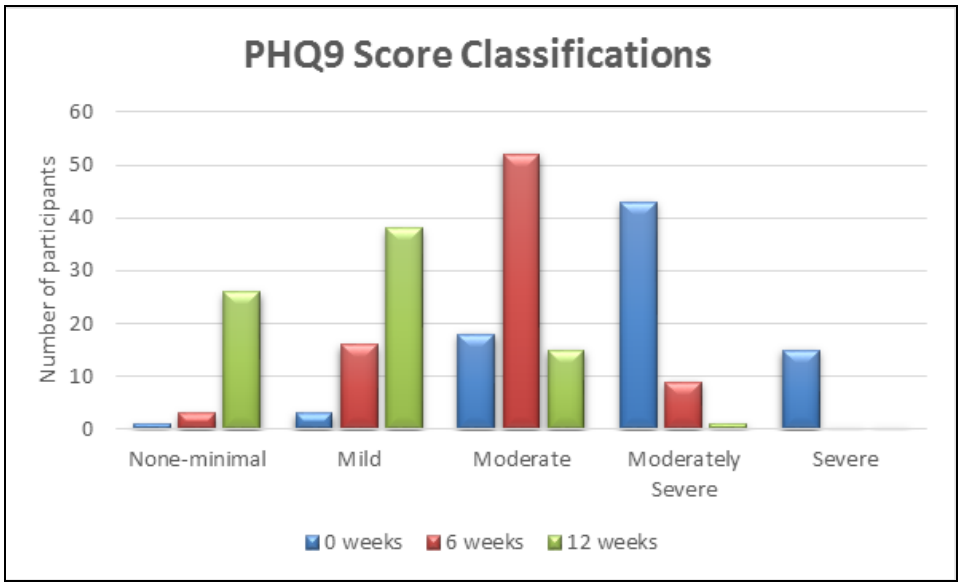


Figure 3: PHQ-9 scores at Week 0, 6 and 12

Ninety-five of the 100 participants had their levels of depression reduced by at least one level (Table 7). Of the five patients who showed no change in level, four patients had a PHQ-9 score of ≤9 at Week 0 and the remaining patient decreased in score from 13 (moderate) at Week 0 to 10 by Week 12.

Table 7: Decrease in Levels for PHQ-9 Score During the Programme

Number of Levels Decreased	Number of Patients
4	11
3	15
2	35
1	34
0	5

Overall, 73 of 100 patients started with a PHQ-9 score ≥10 and these had reduced to ≤9 by Week 12.

8.2.6 Patient Satisfaction Survey

8.2.6.1 Patient Waiting Times

It was not possible to fully calculate how long patients waited for a referral to the LGA programme as there were inconsistencies in completing the questionnaires. However, from the data it is evident that no patient waited more than a month and that the majority of patients waited only days.

8.2.6.2 Patient Perceptions

At the end of the programme, 78% of patients said that they now felt more in control of their health.

The introduction to diabetes workshop, nutrition workshop and healthy cooking workshop was found helpful by 87%, 69% and 60% of patients, respectively.

8.2.6.3 What Are You Doing Now

Responses to "what are you doing now" questions are shown in Figure 4 below. The figure shows that the LGA programme had a lasting impact on participants in that they have adopted one or more healthy lifestyle attributes as a result.

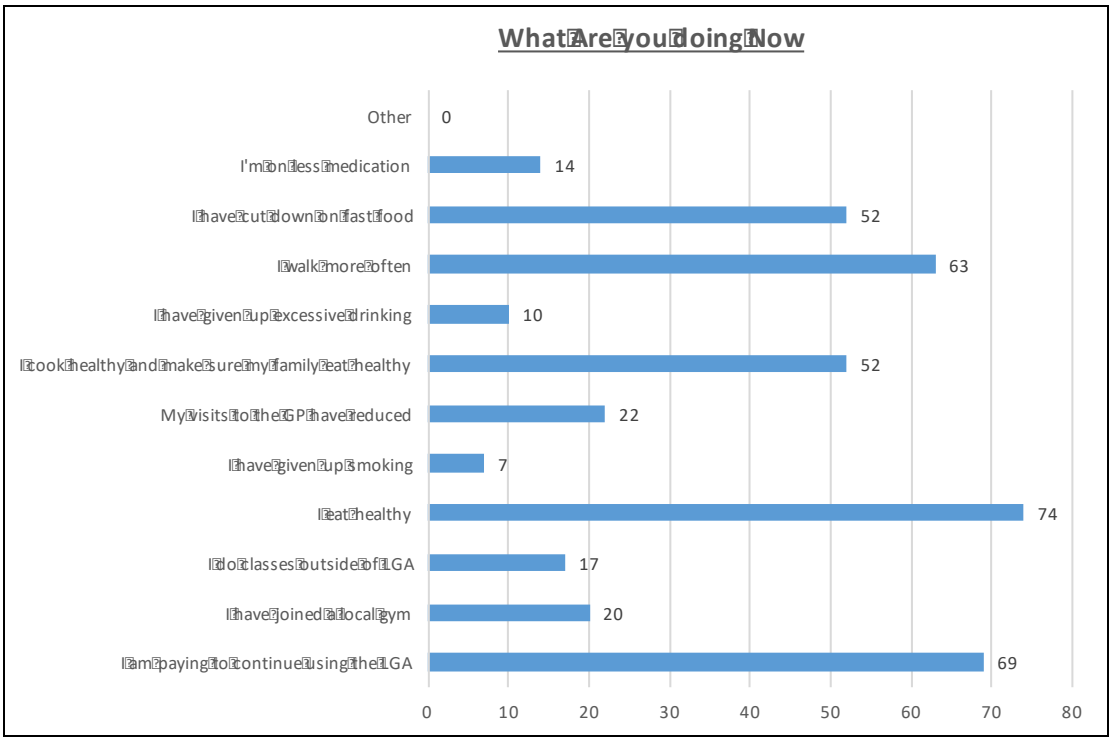


Figure 4: Patient Satisfaction - What Are You Doing Now?

The number of positive lifestyle attributes that patients acquired from the LGA programme are shown in Table 8. All patients adopted at least one healthier lifestyle attribute. A weighted calculation showed that the average patient adopted 4.00 healthy lifestyle attributes.

Table 8: Number of Positive Attributes Adopted

Number of Positive Attributes	1	2	3	4	5	6	7	8	9	10	Total
Number of Patients	9	3	22	31	24	6	3	1	0	1	100

8.2.6.4 If You Enjoyed the LGA Programme – Please Tell Us Why?

Figure 5 shows that the LGA programme was well received with excellent feedback. Amongst the overwhelmingly positive feedback, it is notable that 100% of participants found the staff to be friendly and also saw the benefits of attending the programme.

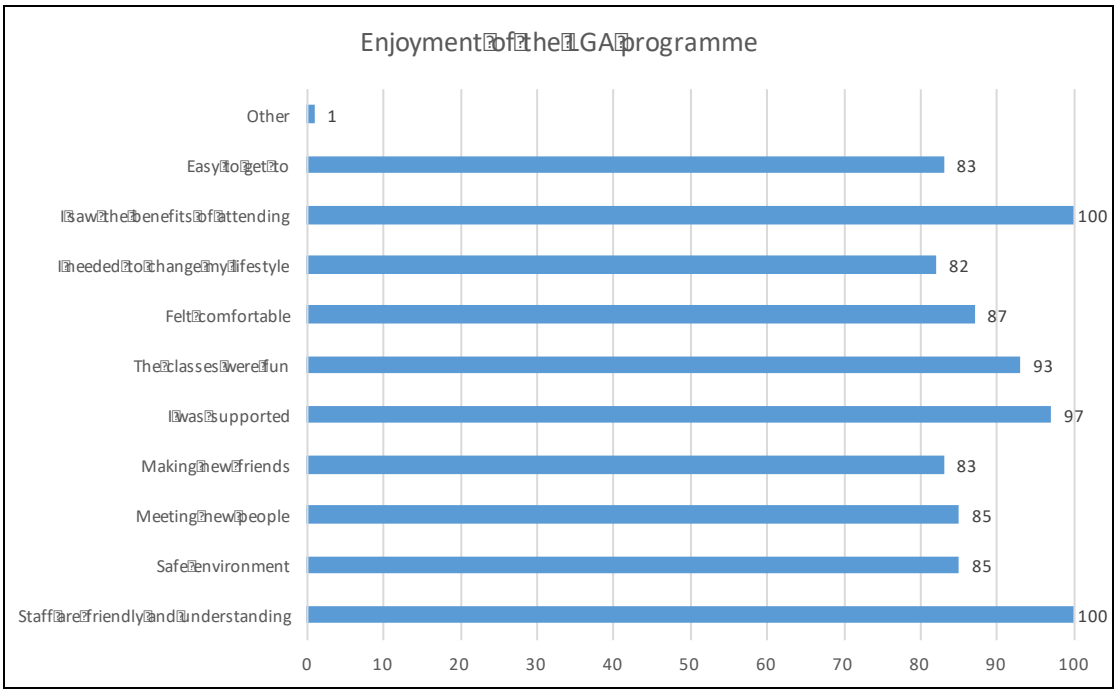


Figure 5: Patient Satisfaction - Enjoyment of the LGA Programme

8.2.6.5 How can we improve?

While the feedback was undoubtedly positive, there were some areas where there could have been improvements, although some of these "problems" such as busy classes were as a result of the LGA programme's success (Figure 6).

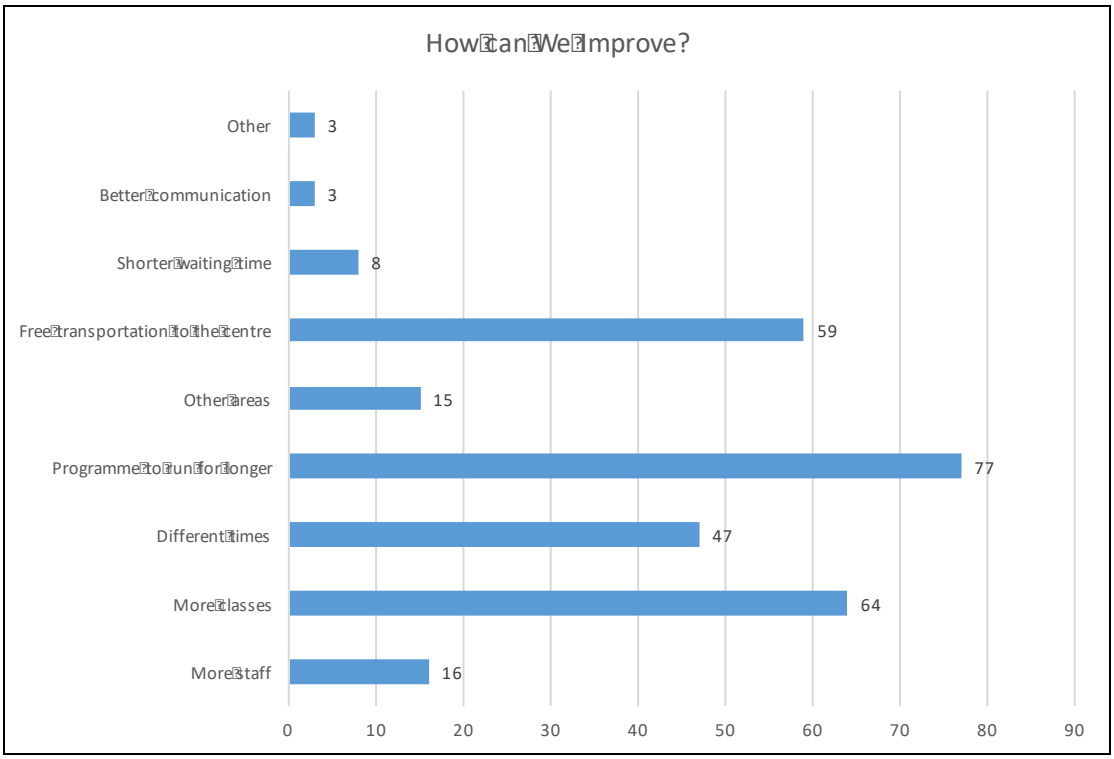


Figure 6: Patient Satisfaction - How Can We Improve?

Over 75% of the participants would have liked to have seen the programme run for longer. This is a testament to the popularity and success of the LGA programme.

8.2.6.6 If You Didn't Enjoy the Programme - Please tell us why

This section received six responses. Of these, three said it was hard at first but it got easier. This is encouraging as it was the intention of the programme to make participants fitter and feel better about themselves. Two responses were about the classes being busy. Again, this has a positive aspect because had the programme not been effective then people would have stopped attending and classes not been as busy.

1. The first 2 weeks were hard.
2. Classes are busy.
3. At first I did not like it as it was hard. As I progressed it became easier.
4. Crowded.
5. ?Little far? (text unclear)
6. Found it hard at first, but became a lot easier.

8.2.6.7 Comment - Anything Else

The majority of responses echoed the "How can we improve our service" Section with responses on the themes of longer programme time, free transport, more classes and more regional areas covered. All responses are listed in Appendix 4. The remainder of responses in this section which didn't echo what the responder had put in another section were ALL about how good the programme was and how much it had benefited them and in some cases, their families too.

A video about the programme is available at https://youtu.be/NACjPT7ZT5A

9 SUSTAINABILITY OF EFFECT

Follow-up was obtained for 50 patients selected at random from the 2015/16 participants in the LGA programme. Results are provided in Appendix 3.

Of the 45 patients for which body weight was available in April 2018, the average weight loss between the end of their LGA programme and April 2018 was 2.26 kg. Of the 45 patients, 42 had lost weight (ranging from - 0.1kg to - 14.5 kg), and 3 patients had stayed the same weight. None of the patients evaluated had gained weight.

10 COST

Oldham CCG approved a grant of £80,000 for the project for 12 months over 2017/18, as follows:

Table 9: Cost of the LGA Programme

Item	Units	Cost per Unit	Sub-total
Project Supervisor	1	£16,200.00	£16,200.00
Personal Trainers	1	£15,600.00	£15,600.00
Administrator	1	£14,400.00	£14,400.00
Sessional personal trainer to cover the 3 venues	1	£5,000	£,5000
Venue hire (OBA, our main base)	1	£12,000.00	£12,000.00
Venue Hire Honeywell Centre	1	£7,200.00	£7,200.00
Venue Hire Pakistani Community Centre	1	£7,200.00	£7,200.00
Desmond Training for staff to deliver in Bangla/Urdu	3	Aprox: £400	Aprox: £1200
Cooking Class (one per month)	12	£100	£1200
		Total	£80,000

It is anticipated that by the end of the 2017/18 programme, 200 patients will have participated in the programme. The resultant cost is £4.76 per day per patient (£400 per patient in total).

It should also be noted that although there are costs incurred in hiring local facilities, many of these are owned by the local authority and so the programme also has value in using community assets. The use of community buildings in areas where engagement has historically been difficult has helped to create community in these areas. The overwhelmingly positive feedback from the patient satisfaction survey shows empowerment of participants to use their community facilities. However, without the hiring costs charged by Oldham Council (£24,000), the cost per person would reduce considerably.

Cost savings represented by the programme are from the number of patients meeting HbA1c and blood pressure targets, reducing the risk of diabetic and cardiovascular complications. Reducing HbA1c results in fewer microvascular complications and reduced treatment cost (Baxter et al, 2016), and a reduction in QRISK score represented fewer anticipated cardiovascular events, with each cardiovascular event avoided saving approximately £2400. Results from the LGA 12-week programme show an overall 5.6% relative risk reduction of cardiovascular events using QRISK. Therefore, the programme can be expected to save the NHS approximately £14,400 over the next ten years for each 100 participants. Taking social value into account, the mean QALYs preserved per cardiovascular event avoided are 0.7934 per patient, or £15,808 per patient (based on a QALY having a value of £20k) (Ward, 2005).

Further, a 1% reduction in HbA1c in type 2 diabetic patients has a predicted gain of 0.413 QALYs (McEwan, 2010). The present study showed a reduction of 7.8%, representing 3.2 QALYs and £64K saving per type 2 diabetic patient.

The improvement of depression symptoms described above is also anticipated to reduce social and medical costs in patients who participate in the programme. The programme is therefore an extremely effective use of resources.

11 DISCUSSION AND OVERALL CONCLUSIONS

The LGA programme met its objectives. Namely, there were:

- Reductions in the number of patients with HbA1c ≥58 mmol/mol (from 27 patients at Week 0 to 20 patients at Week 12)
- Reductions in the number of patients with blood pressure ≥140/80 mmHg (from 26 patients at Week 0 to 10 patients at Week 12)
- Delivery of a structured education course for people with diabetes diagnosed for less than a year

The LGA programme has shown remarkable improvements across all areas measured. Patients on the 12-week programme experienced, on average, a 4.4 mmol/mol reduction in HbA1c, a 5.2 mmHg reduction in systolic blood pressure and a 3.5 mmHg reduction in diastolic blood pressure. Patients had an average reduction in QRISK of 0.84 points. On average, patients lost 2 kg and reduced their BMI by 0.8 kg/m^2.

There was a very strong trend away from clinically depressed PHQ-9 scores. Overall, 73 of the 100 participants started with a PHQ-9 score of ≥10 but had reduced this figure to <9 by Week 12. By Week 12, none of the patients were severely depressed (reduced from 20) and the majority of patients had no / minimal depressive symptoms (39 patients) or mild depressive symptoms (43 patients). Over the course of the study, depressive symptoms were resolved in 36 patients. This has wide-reaching implications for the ability of these individuals to work and to reduce their need for other support services.

The program was delivered with minimal wait and resulted in 78% of patients saying that they felt more in control of their health. All patients adopted at least one healthy lifestyle attribute (the average was four). Patient satisfaction was high with overwhelmingly positive feedback, and 100% of patients found staff friendly and saw the benefits of attending.

Furthermore, the effect of the program is sustainable. Of 50 randomly selected patients, followed up from their participation in the LGA programme in 2015/16, data were available for 45 patients. The average continued weight loss to April 2018 was 2.26 kg, with 42 patients losing more weight and 3 patients staying at the weight they were at Week 12.

Cost per patient for this program is anticipated to be £400, based on 200 patients enrolled. Approximately 30% of these costs are venue hire, charged by Oldham Council. It was noted during the programme that the limiting factor in enrolling patients was the process of obtaining HbA1c results within the required window for the study. However, there is the possibility of issuing patients with kits to test HbA1c themselves. Without the above constraints, it is anticipated that the number of enrolled patients could be doubled, which would dramatically reduce the cost per patient to £140. For comparison, funding of other weight loss schemes, without the physical exercise component, already cost in excess of £300 per person. The current

programme as it stands therefore adds considerable value over existing schemes and represents considerable long-term cost savings in terms of use of health services; it also has the potential to be refined to an even more cost-efficient programme.

The LGA program is an example of real community engagement in populations that have been difficult to access. The programme represents effective value for money by initiating a change of habits throughout patient communities; improving mental and physical health; and making use of council owned buildings and reducing the reliance on health care services. The extraordinary improvement in mental health shown from this programme indicates the programme's success in reaching out to previously hard-to-engage-with communities, who now feel heard and supported. Additional benefits of the programme include:

Engagement and Empowerment (Confident Communities)

- Enhanced communications, engagement and trust with the population
- Enhanced engagement with GP practices
- Empowered people to take responsibility for their own health
- Enhanced engagement with BME/Hard to reach/Women/Men
- Reduced social isolation, and opportunity to meet and make friends
- Enhanced social value
- Social and personal development
- Listening to communities and delivering services to meet their needs

Physical Health Improvements

- Knowledge of healthy eating and practical lessons to take back into the home and family
- Knowledge on diabetes prevention and management
- Weight loss
- Reduction in blood pressure
- Introduction to regular exercise
- Support for patients to sustain their health improvements and cope with long term conditions

Mental Health Improvements

- Drastically improved mental health and positive mental attitude
- Enhanced quality of life
- Reduction in stress

Employment Opportunities

- Employ 4 staff and 18 sessional staff from local community
- Aid volunteering
- Aid getting people back into work
- Certificate in food hygiene

Cost Saving Benefits

- Better management of long term conditions
- Reduced reliance on services
- Introducing use of community buildings and building the communities to use them

12 REFERENCES

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Ward S, Lloyd Jones M, Pandor A, et al (2005) Statins for the prevention of coronary events. Technology assessment report commissioned by the HTA Programme on behalf of the National Institute for Clinical Excellence.

13 APPENDICES

Appendix 1: Sample Programme and Patient Diary

IMG-20180419-WA0023.jpg

5572 - Diary Booklets PROOF.pdf

Appendix 2: Service Questionnaire

Patient service.pdf

Appendix 3: Results

Let's Get Active Interim Data May 2018 100 Participants.pdf

LGA 50 patients followed up from 15-16 program.pdf

Appendix 4: Reports

Statistics Report.pdf

LGA PHQ9 100 Subjects May 2018.pdf

Let's Get Active Participant Satisfaction Survey 2018.pdf

Appendix 5: Protocol

LGA Evaluation Protocol Jul 2017 v2.0.pdf