RediCareControl DTx

Preliminary Study Results: Homewell Practice

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Summary

Background:

There is strong evidence that lifestyle therapy which focuses on patient education, improving health literacy, dietary advice, increasing physical activity and access to human support when required can be effective in improving metabolic health. Delivering in person lifestyle therapy is difficult to scale and deliver consistently. There is a perception that digital or in person lifestyle therapy is not effective in multi morbid, polypharmacy patients with long term chronic conditions, particularly in those who are living in areas of socioeconomic deprivation.

RediCare Control is a digital therapeutics platform designed to support and empower patients to self-treat and manage chronic conditions such as; Pre- Diabetes, Type 2 Diabetes mellitus, Hypercholesterolaemia/Dyslipidaemia, Hypertension/Prehypertension, Overweight/Obesity Conditions. Working in partnership with BarlowCollins who have a deep understanding of primary care, we have developed an understanding of how to bring digital therapeutics to life within a British General Practice setting.

A**im:**

In conjunction with Barlow Collins, this study sets out to examine the effect of a Digital Therapeutic, RediCare Control, delivered in a primary care setting in conjunction with a multi-disciplined team on multi morbid patients with severe metabolic syndrome in a socially deprived area.

Design and Methods:

A cohort of c. 130 patients with multi morbidity and severe metabolic syndrome were identified within the Homewell Practice using a data search from the EMIS platform. These patients were informed about the program via an outbound marketing campaign using SMS, Emails, Videos and Webinars. Patients were also individually referred onto the intervention via referral by their doctor, diabetic nurse and or prescribing pharmacist. 41 Patients (c. 32%) elected to partake in the treatment and registered onto the RediCare Control platform. Prior to program start each patient had a consultation with a doctor or health care professional, the following clinical measurements were taken: HbA1c, Lipid Profile, Weight, Height, Waist Circumference, Blood pressure. At program start, the average HbA1c was 72.8 mm/mol, BMI 37.1, Weight 106.5kgm, Systolic Blood Pressure 142.4 mm hg and Systolic Blood Pressure 88.8 mm Hg. Many of these patients were Insulin dependent on GLP1's and antihypertensive medications. Patients who were insulin dependent or on GLP1's were advised to monitor their blood glucose levels closely and were advised to reduce their daily insulin dosage by 50% as blood glucose levels reduced.

Once patients had their blood and physical measurements and bloods taken, they were shown how to register online to use RediCare Control.

During treatment RediCare Control Health coaches remotely monitored participant progress such as health education consumed, dietary recipes downloaded, weight and blood glucose logs. They were offered and encouraged to access unlimited online consultations with a health coach and use the moderated peer to peer support functionality to answer any queries they might have in terms of managing their health. A weekly webinar for all participants was provided, this webinar involved the RediCare and Homewell multidisciplinary team members and consisted of discussions around the management of Type 2 Diabetes, Blood Pressure etc with interactive question and answer sessions.

Patients received regular snippets of health education delivered via email, these were short 30 second video-based messages which summarised the health learnings and encouraged further engagement with the structured video education on the platform and implementation of the dietary and exercise protocol.

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Results:

41 participants registered for the intervention and attended follow-up after 16 weeks. Of the 41 participants 31 (76%) were deemed to have engaged, i.e. consumed some element of health education within the platform or attended a weekly webinar.

For those who engaged the mean reduction from a baseline of 72.5 mmol/mol in HbA1c was 16.6 mmol/mol (22.9%) Mean body weight reduction from baseline (*M*= 104.7) to follow up (*M*=99) was 5.7 kg (5.5%) There were statistically significant changes in the following clinical parameters from baseline to follow-up BMI -2.0 (5.5%), Waist circumference -6.7 cm (5%), waist to height ratio (5.6 %), Systolic blood pressure (-4 mmHg), Diastolic blood pressure (-6.7 mmHg), Triglycerides (-0.46 mmol/l)

Analysis of patients with very elevated HbA1c showed significant improvements. Patients with a baseline Hba1C >70 (n=14) saw a 29.5 mmol/mol reduction (-32%) at 16 weeks. Patients with a baseline Hba1C >85 (n=9) saw a 37.6 mmol/mol reduction (-37%) and patients with a baseline Hba1C >100 (n=4) saw a 47.8 mmol/mol reduction (-41%)

Patients who were stage 2 Hypertensive (n=26) showed a 6 mmHg and 9 mmHg systolic and diastolic reduction respectively.

Morbidly obese patients with BMI >40 (n=8) had clinically significant BMI reduction of 2.6 (6%) weight loss of 8kgs (6%)

Significant medication reductions and in some case eliminations were observed in Type 2 Diabetic patients.

The high volume of recruitment, 41 (c. 32%) participants from c. 135 who were offered treatment suggests that patients are far more likely to partake in lifestyle therapy when a referral is made by their Doctor, Prescribing Pharmacist or specialist Diabetes Nurse.

Conclusion

RediCare Control delivered in a primary care setting setting in conjunction with a multi-disciplined team with was highly effective in treating multi-morbid, insulin dependent patients in a socially deprived area. Patients with very elevated baseline HbA1c and or morbid obesity respond well to the RediCare Control Digital Therapeutic.

Clinical Outcomes Summary

Patient Data		
Population Metric	# of Patients	Average Age
Population Metric	41	57
Males	21	57
Females	20	58

Compliance Analysis	
Total # of Patients	41
# of Compliant Patients	31
# of Non Compliant Patients	10
Percentage Compliance	**76%**

Weight Analysis (N=41)				
Population Metric	**T1**	**T2**	**Δ**	**Δ%**
Population ***	106.5	102.5	-4.1	-3.8%
Compliant Population	104.7	99.0	-5.7	-5.5%
Non-Compliant Population	111.5	111.9	0.4	0.4%

Body Mass Index Analysis (N=41)				
Population Metric	**T1**	**T2**	**Δ**	**Δ%**
Population ***	37.1	35.7	-1.4	-3.8%
Compliant Population	36.5	34.6	-2.0	-5.4%
Non-Compliant Population	38.5	38.6	0.1	0.3%

Waist to Height (N=38)				
Population Metric	**T1**	**T2**	**Δ**	**Δ%**
Population ***	0.71	0.67	-0.04	-5.0%
Compliant Population	0.71	0.67	-0.04	-5.6%
Non-Compliant Population	0.72	0.69	-0.02	-3.1%

Waist (N=41)				
Population Metric	**T1**	**T2**	**Δ**	**Δ%**
Population ***	120.2	114.2	-6.0	-5.0%
Compliant Population	119.2	112.6	-6.7	-5.6%
Non-Compliant Population	123.1	119.3	-3.8	-3.1%

HbA1c Analysis (N=41)				
Population Metric	**T1**	**T2**	**Δ**	**Δ%**
Population***	72.8	61.4	-11.4	-15.7%
Compliant Population	72.5	55.8	-16.6	-22.9%
Non-Compliant Population	74.0	78.6	4.6	6.2%

Systolic Blood Pressure Analysis (N=41)				
Population Metric	**T1**	**T2**	**Δ**	**Δ%**
Population	142.4	140.8	-1.7	-1.2%
Compliant Population	144.8	140.8	-4.0	-2.8%
Non-Compliant Population	136.0	140.7	4.7	3.5%

Diastolic Blood Pressure Analysis (N=41)				
Population Metric	**T1**	**T2**	**Δ**	**Δ%**
Population ***	88.8	83.2	-5.6	-6.3%
Compliant Population	90.8	84.2	-6.7	-7.3%
Non-Compliant Population	83.3	80.5	-2.8	-3.4%

Triglycerides Analysis (N=39)				
Population Metric	**T1**	**T2**	**Δ**	**Δ%**
Population *	2.80	2.43	-0.37	-13.2%
Compliant Population	2.80	2.34	-0.46	-16.4%
Non-Compliant Population	2.82	2.74	-0.08	-2.8%

High Density Lipoprotein Analysis (N=39)				
Population Metric	**T1**	**T2**	**Δ**	**Δ%**
Population *	1.24	1.29	0.05	3.9%
Compliant Population	1.24	1.31	0.07	5.9%
Non-Compliant Population	1.23	1.19	-0.05	-3.6%

*** Significant at 1% Level

** Significnat at 5% Level

* Significant at 10% Level

HbA1c Analysis

HbA1c Movement Summary			
Category	N	Δ	Δ%
HBa1c >70	14	-29.5	-32%
HBa1c > 85	9	-37.6	-37%
HBa1c > 100	4	-47.8	-41%
Population	**27**	**-38.3**	**-37%**

Highly effective in patients with very elevated HbA1c

Hypertension Analysis

Hypertension Summary	
# of Patients Presenting with Hypertension	26
# Moved out of Hypertension	6
Mean Systolic Blood Pressure - Week 1	149
Mean Diastolic Blood Pressure - Week 1	94
Systolic Blood Pressure Δ (mmHg)	-6
Systolic Blood Pressure Δ%	-4%
Diastolic Blood Pressure Δ (mmHg)	-9
Diastolic Blood Pressure Δ%	-10%

In Hypertensive persons, a 6mm and 9mm systolic and diastolic blood pressure reduction was observed

6 persons moved down a stage, 1 Person moved up a stage

Morbid Obesity Analysis

BMI Analysis of Patients Greater than 40 KG/M^2	
Total Number of Patients	12
Average T1 BMI	44.6
# of Compliant Patients	8
% Compliance	67%
# Moved Category - BMI < 40	3 (25%)
Total Population Δ	-1.9
Total Population %	-4.2%
Compliant Population Δ	-2.6
Compliant Population Δ%	-6%

Effective in patients with BMI's > 40 with a reduction of -2.6 points

Case Studies

The following are collection of case studies from the HomeWell study which describe clinical outcomes achieved by participants, some of which were beyond the study's primary measurement objectives.

Case Study 1: Bryan – Hypertension down 1 stage and improved HbA1c

Pre and Post Biometrics:

Weight: 103.8 kgs to 94.6 kgs

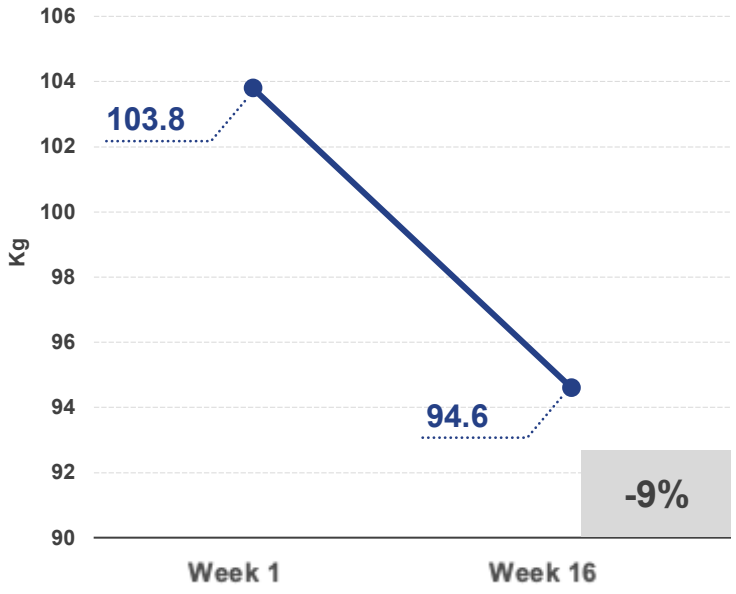
B.P: 163/84 to 129/68

HbA1c: 48 to 44 mmols/mol

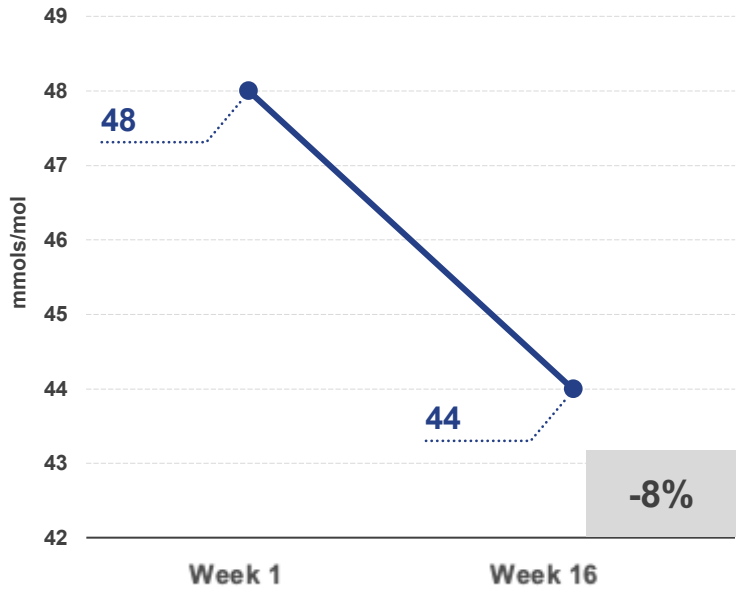
TG's: 1.6 to 0.6 mmols/mol

BMI: 35.5 to 32.4

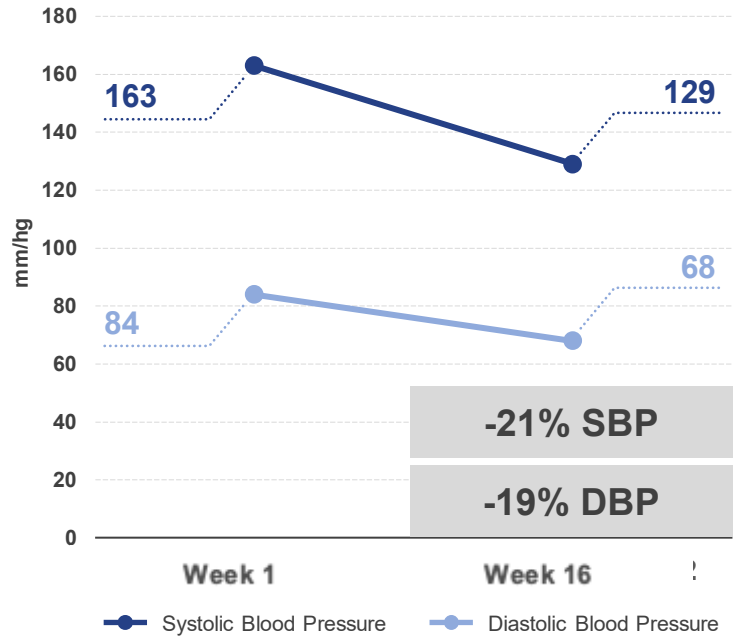
Weight



HbA1c



Blood Pressure



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Background

Bryan, a 67-year-old male retired professional started the RediCare Control programme after being contacted by his G.P in relation to his Type 2 Diabetes. Bryan also suffered from high blood pressure (163/84 mm Hg) and was obese with a pre intervention BMI of 35.5. Bryan found the video based personalised health education easy to understand and implement and commented that his hunger level reduced significantly very quickly, and he never had food cravings. Bryan engaged with his health coach to answer any specific queries he had and regularly attended webinars which he found very interesting. After a period of 16 weeks, Bryan's diabetic status improved as his HbA1c reduced from 48 mmols/mol to 44 mmols/mol. Bryan lost 9.2kg (8.9% of body weight) his BMI reduced by 3.1 points, his blood pressure reduced from 163/84 to 129/68. Bryan also reduced his triglycerides by 62.5%, falling from 1.6 mmols at programme start to 0.6 mmols.

Discussion

This is an interesting case of very significant clinical improvements across many conditions in a very short period of time. Bryan reduced his HbA1c, significantly reduced his blood pressure, triglycerides and reduced his weight by 9.2kg. Bryan commented that this was done without feeling hungry or deprived and it was very easy to implement. Bryan has now have gained the health literacy, fluency and confidence to self-manage his health going forward.

Nicky – Type 2 Diabetes, Hypertriglyceridemia and Mental Health

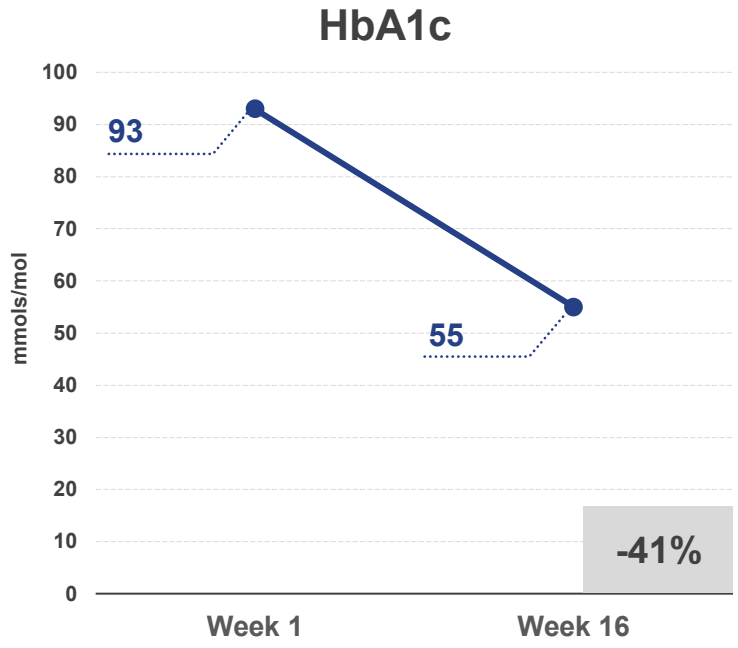
Pre and Post Biometrics:

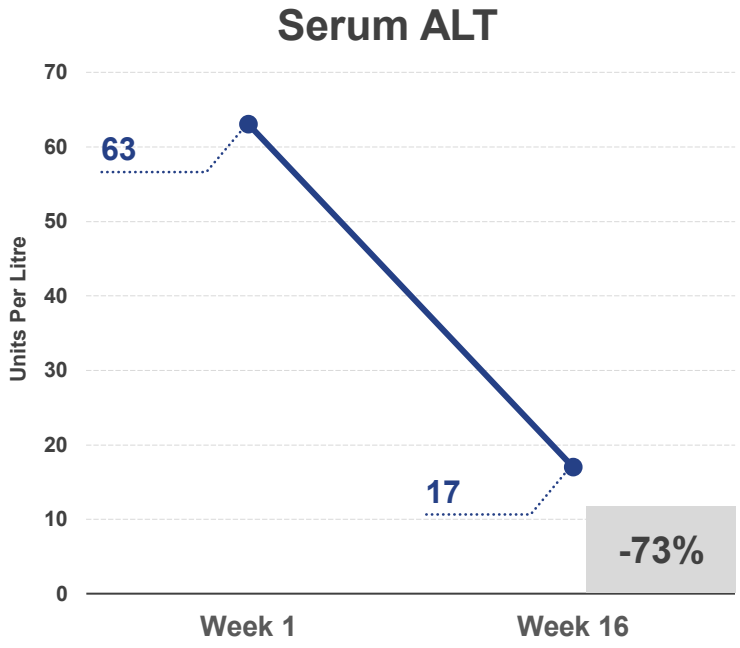
Weight: 99.6 kgs to 88.9 kgs

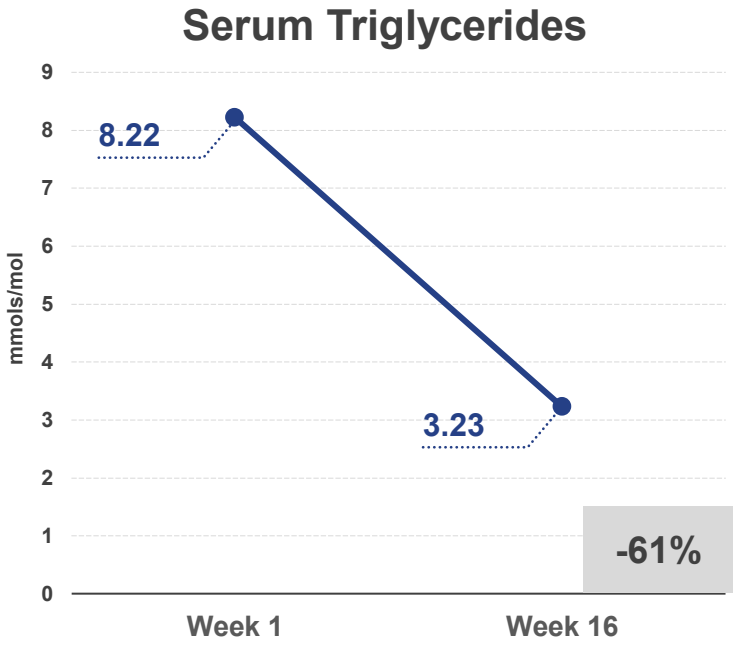
B.P: 158/83 to 140/86

HbA1c: 93 to 55 mmols/mol

TG's: 8.2 to 3.2 mmols/mol







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Background

Nicky, a 54 year old female started the RediCare Control programme after being contacted and referred by her doctor. Nicky was 99.6 kgs at programme start and presented with stage 2 hypertension, poorly controlled Type 2 Diabetes, and Hypertriglyceridemia. Nicky also suffers from depression and anxiety.

Nicky accessed the RediCare Control programme and used the online education and resource packs provided. She also regularly attended the programme webinars. She found the programme easy to understand and implement and commented that she was never hungry. Nicky regularly engaged with her health coach where any queries she had about the programme were addressed via video consultation. After a period of 16 weeks, Nicky's HbA1c reduced from 93 mmols/mol to 55 mmols/mol. Nicky lost 10.7kg (10.6% of her body weight). Her blood pressure reduced from 158/83 to 140/86. Her triglycerides reduced by 61%, reducing from 8.2 to 3.2 mmols. Her alanine aminotransferase (ALT) reduced significantly from 63 to 17 U/L suggesting an improvement in liver function.

Discussion

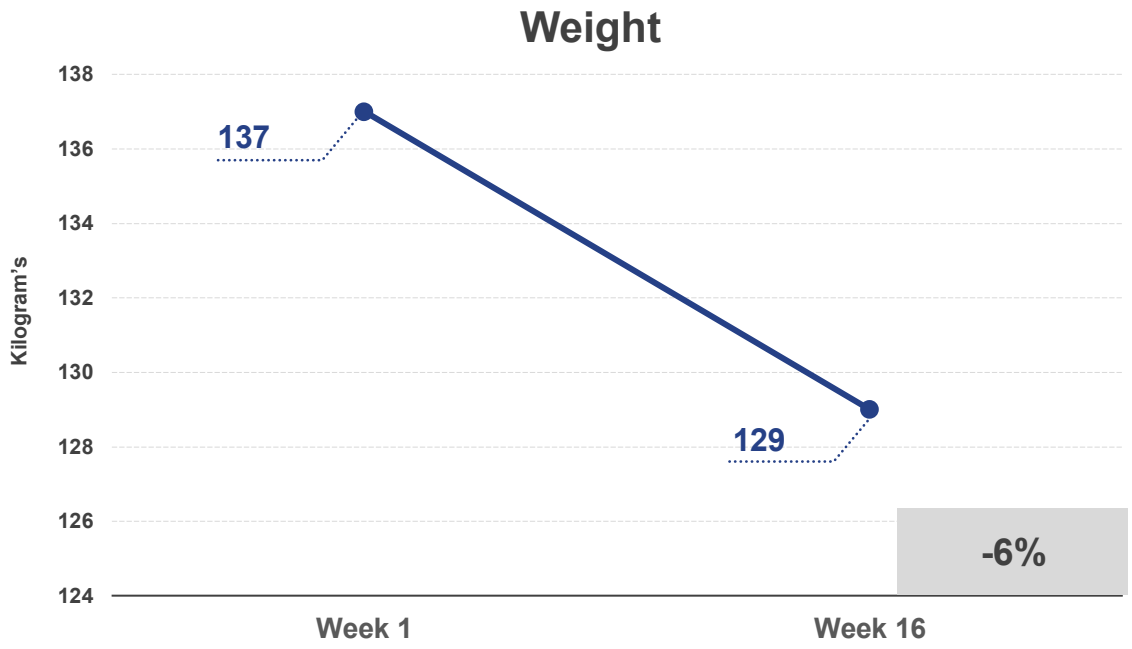
Nicky responded well to RediCare Control. She achieved significantly better glycaemic control within 16 weeks and saw significant improvements in her weight, blood pressure, liver function markers and lipid profile. Nicky also commented that her mental health and overall mood is much improved

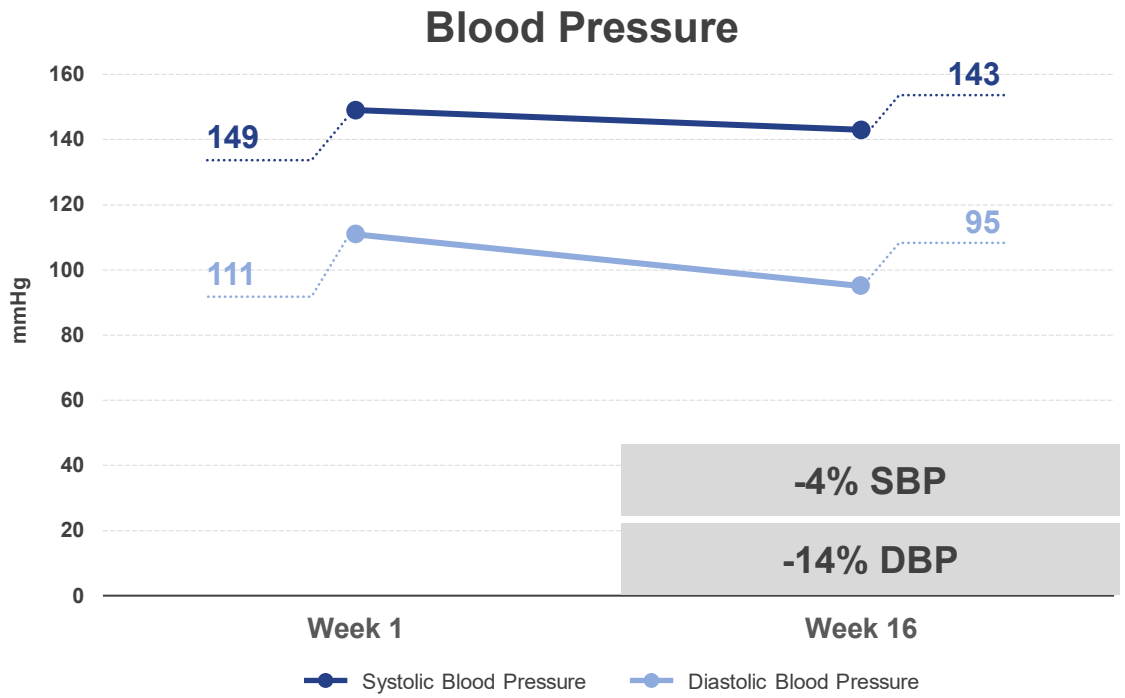
Paul - Foot Ulcers & Medication Elimination

Pre and Post Biometrics:

Weight: 137.4 kgs to 129 kgs

B.P: 149/111 to 143/95





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Background

Paul started RediCare Control after being contacted and referred by his doctor in the Homewell Practice. Paul was 137.4 kgs at programme start and presented with stage 2 hypertension, Type 2 Diabetes and was on metformin, insulin and a GLP-1 agonist. Paul suffered from foot ulcers and was attending the Homewell clinic on a regular basis to have his foot ulcers dressed.

Paul accessed the RediCare Control programme and used the online education to improve his knowledge of his condition and how he could self treat and self-manage his health on an ongoing basis. Paul also engaged with his health coach via video consultations to get answers to any specific queries he had. After a period of 16 weeks, Paul's HbA1c remained stable at 48mmols/mol. However, Paul has stopped all of his Type 2 medications including metformin, insulin and a GLP-1. Paul lost 8.4kg (6.1% of his body weight) and his blood pressure reduced from 149/111 to 141/89. Paul's foot ulcers have fully healed and he no longer has ulcers.

Discussion

Paul feels he has a new lease of life since engaging in the programme. He is now managing his Type 2 Diabetes with simple lifestyle changes and currently without medications and has seen significant improvements in his weight and blood pressure. Paul no longer has ulcers or pain in his feet and no longer needs to attend the Homewell clinic regularly to have his foot dressings changed.

Charlie – Non Alcoholic Steatohepatitis (NASH), Normalised HbA1c

Pre and Post Biometrics:

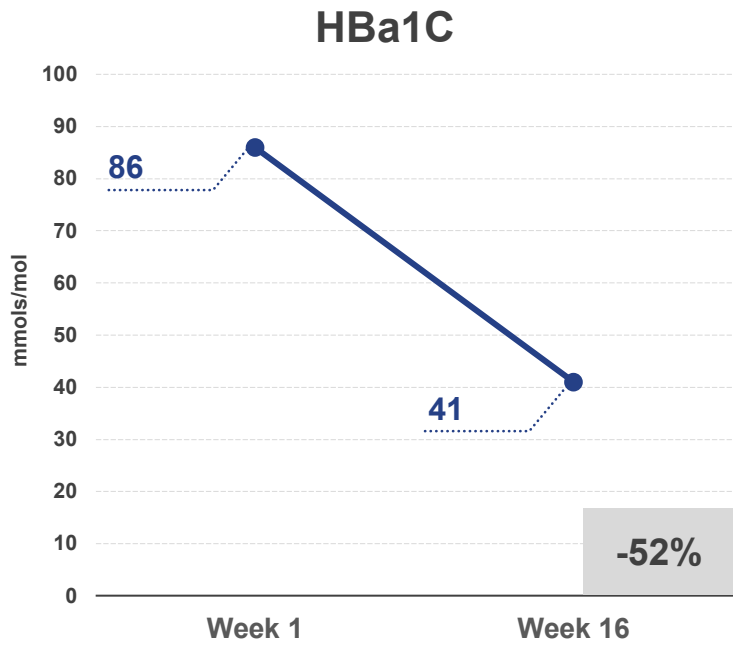
Weight: 124.6 kgs to 109 kgs

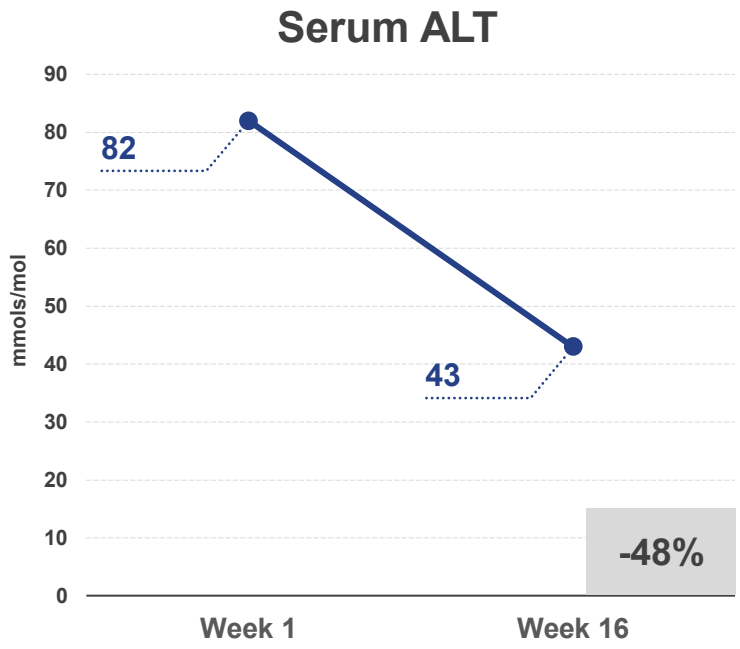
B.P: 149/80 to 126/72

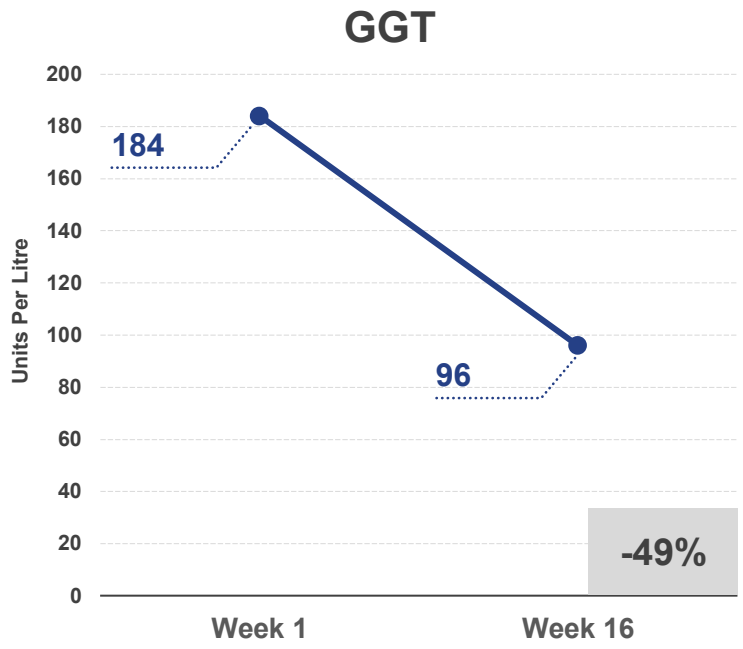
Hba1c: 86 to 41 mmols/mol

ALT: 82 to 43 U/L

GGT: 184 to 96 IU/L







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Background

Prior to joining the RediCare Control programme Charlie had poorly controlled Type 2 Diabetes (86mmol/mol), stage 2 Hypertension and NASH.

Charlie achieved significant health improvements in just 16 weeks on RediCare Control. He lost 15.6 kgs (12.5% of his body weight) and reduced his blood pressure from 149/80 to 126/72. His HbA1c normalised reducing from 86 to 41 mmols/mol. Charlie also saw significant reductions in his markers of liver function, most notably his ALT reduced by 47.5% reducing from 82 to 43 U/L. His GGT also reduced by 53.2% falling from 184 to 96 IU/L.

Discussion

Charlie responded well to the RediCare Control programme. He achieved significant weight loss, normalised his HbA1c and reduced his blood pressure significantly. Before staring the programme Charlie commented that he was worried about his liver function as his hepatologist had raised concern regarding the issue. Charlie was particularly happy with the improvements in his markers of liver function. Charlie found the programme easy to follow and now feels he has the necessary health literacy, fluency and support from RediCare and his GP to better self-manage his overall health going forward.

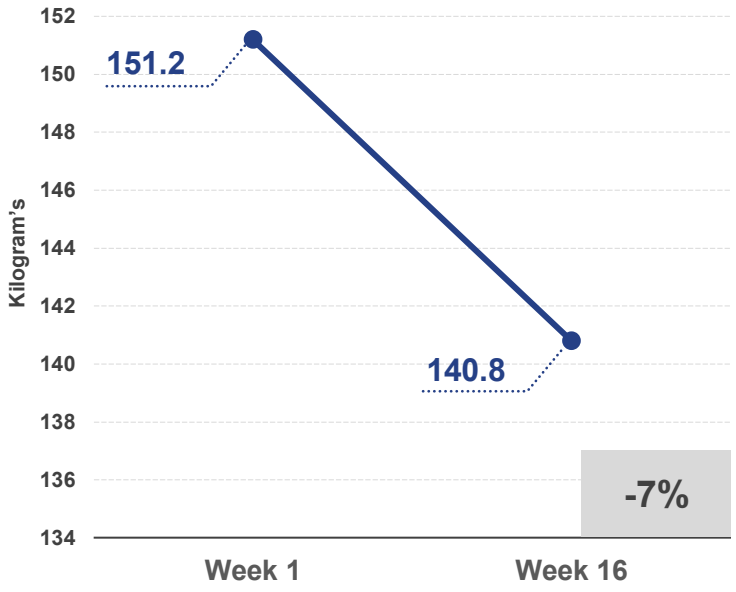
Shaun - Sleep Apnoea

Pre and Post Biometrics:

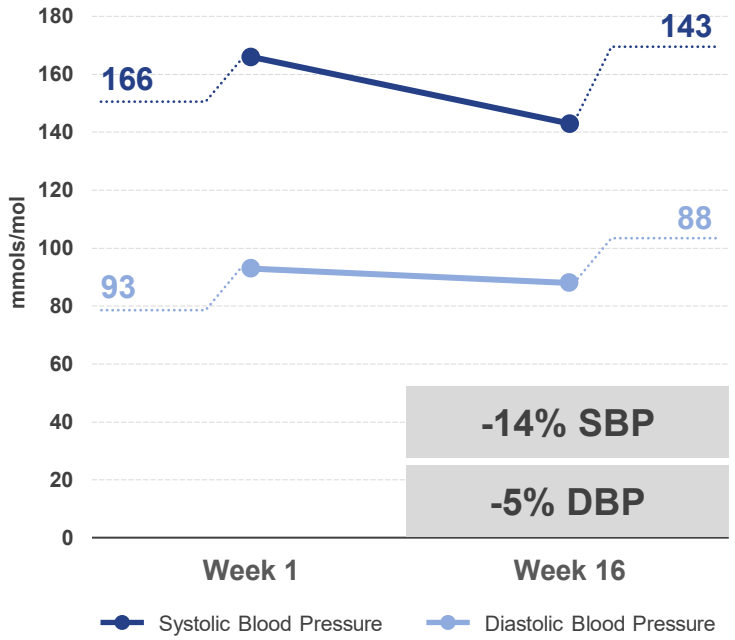
Weight: 151.2 kgs to 140.8 kgs **ALT:** 39 to 19 U/L

B.P: 166/93 to 143/88

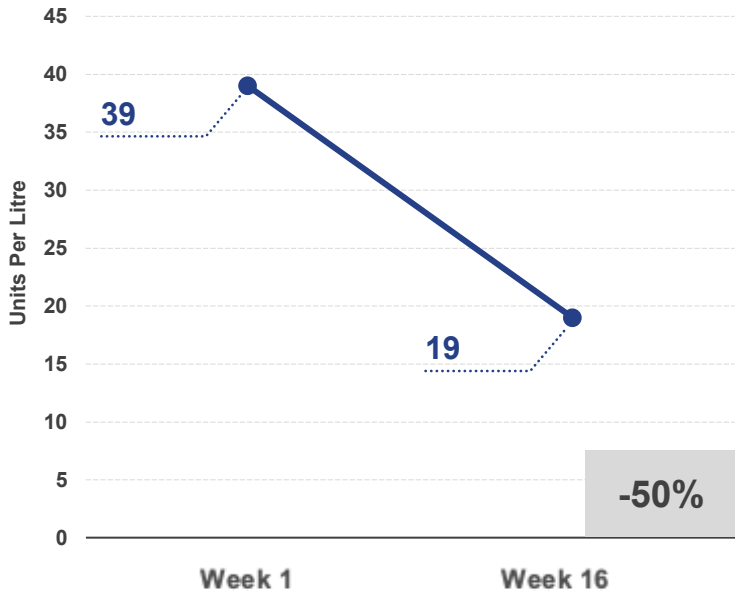
Weight



Blood Pressure



Serum ALT



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Background

Shaun started the RediCare Control after being referred by his doctor. At start of his RediCare journey Shaun presented as morbidly obese, stage 2 hypertension (166/93 mm Hg) and suffered from severe sleep apnoea. Shaun regularly engaged with his RediCare health coach where any queries he had about the programme were addressed via video consultations. Shaun also regularly attended webinars provided as part of the programme.

After a period of 16 weeks, Shaun had lost 10.4 kgs (6.7% of his body weight), his blood pressure reduced from 166/93 to 143/88 and his ALT also reduced from 39 to 19 U/L. Shaun has seen a significant improvement in his sleep apnoea and commented that he no longer wakes up at night having previously woken up 6 to 8 times a night.

Discussion

Shaun responded very well to the RediCare Control programme. Shaun is particularly pleased with the improvement in his sleep apnoea which has improved his qualify of life significantly and he is now getting a full nights uninterrupted sleep. Shaun feels he has now gained the necessary knowledge and tools to continue to self-manage his health going forward.

Patricia – Elevated HbA1c (117) reduced significantly (42)

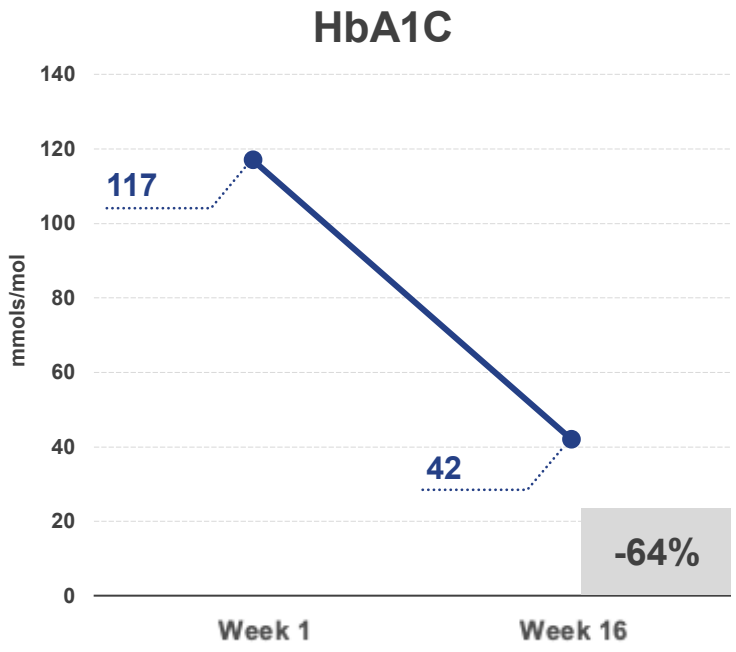
Pre and Post Biometrics:

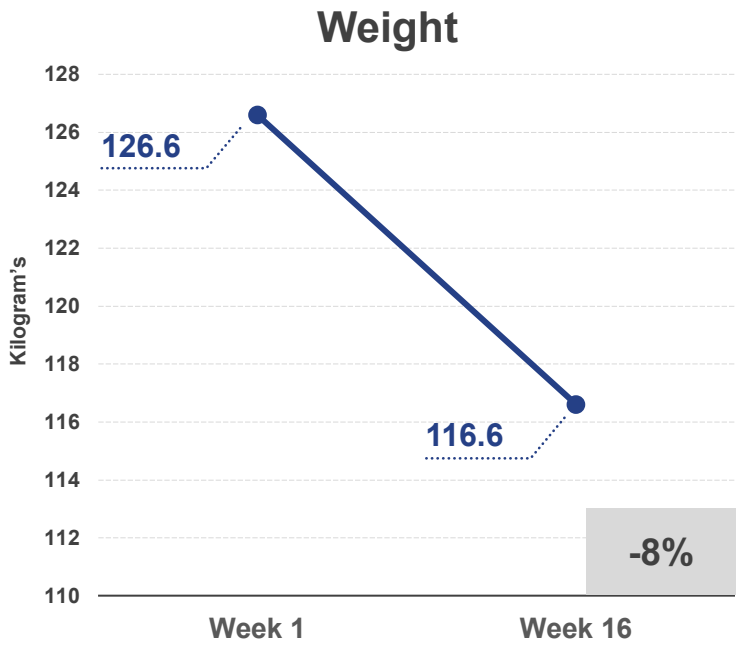
Weight: 126.6 kgs to 116.6 kgs

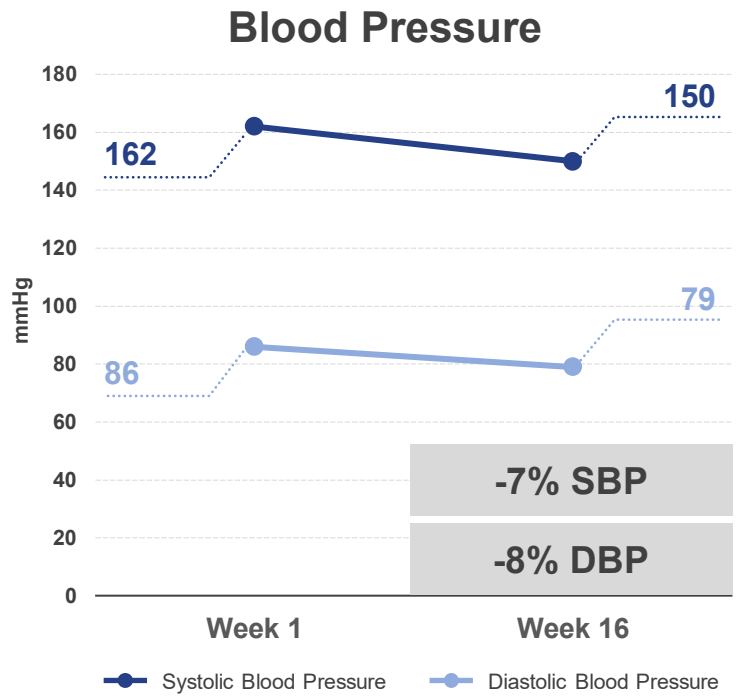
B.P: 162/86 to 150/79

HbA1C 117 to 42 mmols/mol

BMI: 44.3 to 40.8







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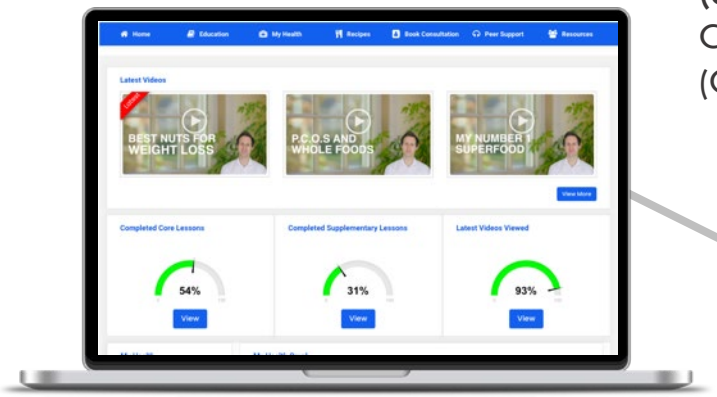
Background

Patricia is a 62 -year-old female who presented with high blood pressure and poorly controlled Type 2 Diabetes and morbid obesity. Patricia's HbA1c at programme start was 117 mmols/mol and her primary goal was to reduce her HbA1c and BMI. Patricia engaged with the programme, consumed the structured education, implemented the dietary advice and watched the short educational video touchpoints and nudges sent to her via email. After 16 weeks on the programme Patricia had lost 10 kgs (7.9% of her bodyweight) equating to a BMI reduction of 3.5 points. Her blood pressure reduced from 162/86 to 150/79. Patricia's saw a 64.1% reduction in her HbA1C which reduced from 117 mmols/mol to 42 mmols/mol.

Discussion

Patricia easily implemented the lifestyle and dietary protocol suggested in the RediCare Control Patricia is a good example of how a poorly controlled Type 2 Diabetic patient can achieve a normalised HbA1c in just 16 weeks. Patricia now feels she fully understands the root cause and how to manage her Type 2 Diabetes. Patricia now also appreciates how the right lifestyle choices around food and moderate exercise can profoundly improve her overall health.

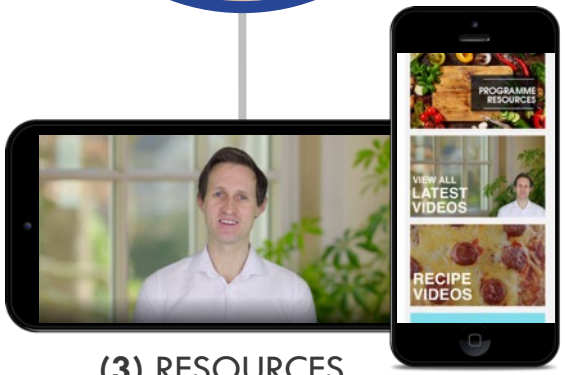
RediCareControl^{DTx} Platform



(1) CHRONIC CONDITION EDUCATION DELIVERED VIA ALGORITHM BASED ON PATIENT NEED

(2) EVIDENCE-BASED DIETARY PROTOCOL

(6) A.I. POWERED CHATBOT SUPPORT (Q3 2021)



(3) RESOURCES

RECIPES, MEAL PLANS, FOOD GUIDES

BIOMETRIC MONITORING

(5) UNLIMITED ACCESS TO 1-1 HEALTH COACH

DOCTOR REVIEWS PROGRESS & ADJUSTS MEDICATIONS (If Indicated)

(4) MODERATED PEER SUPPORT FORUM

RediCare Control is a digital therapeutics platform designed to support and empower patients to self-treat and manage chronic conditions such as; Pre-Diabetes, Type 2 Diabetes mellitus, Hypercholesterolaemia/Dyslipidaemia, Hypertension/Prehypertension, Overweight/Obesity Conditions. The core 5 components of RediCare Control^{DTx} include:

1. **A Personalised Curriculum:** The extent to which patients are educated about their health conditions is considered one of the most important aspects of chronic disease management. Education informs the patient on their condition, its complications and enables patients to understand the root cause of their condition, which is often lifestyle related. RediCare Control^{DTx} includes a comprehensive suite of clinically verified educational content on the chronic conditions we treat. This educational content informs the participant on how simple lifestyle changes in diet, exercise, sleep patterns and motivation can treat and even reverse chronic conditions. This content is delivered via easy-to-understand short video format, enabling participants to learn anytime, anywhere on a mobile device. The therapeutic is prospectively malleable to devise a lifestyle plan catering for the individual needs of the patient which is established by way of algorithm.

2. **Resources to Implement the Learning and Dietary Protocol:** Supporting educational content and the optimised dietary protocol, are all the necessary resources and collateral to enable participants to easily implement the newly acquired health knowledge. These resources include easy to cook recipes, cooking videos, shopping lists, meal plans, visual food rating guides and exercise guidance.

3. **1-to-1 Phone Support and Peer Support:** There is strong evidence that an important part of chronic disease management is ensuring that patients have access to ongoing support, follow-up care and health coaching. RediCare Control^{DTx} offers unlimited access to pre booked 1-to-1 online consultations with qualified health care professionals and access to a moderated peer to peer support platform. This is in addition to the recurrent reminders delivered to the patient nudging them toward a healthier lifestyle. Future releases will incorporate support powered by AI.

4. **Evidence Base:** There is a strong evidence based behind the program, both at meta-analysis/guideline level and via direct studies in real world settings. As part of the research and development process, meals eaten by study participants were tracked and analysed and their effect on body composition, blood pressure, lipid profiles and HbA1c measured. This prior work presented at Euro Prevent 2019 and meta-analyses/guidelines informed the dietary strategy within RediCare Control^{DTx}, which is centred around a “whole food” eating protocol with a very strong emphasis on reducing the consumption of processed food, confectionary, refined carbohydrate and refined sugars.

5. **Ongoing Monitoring and Support:** Patients are monitored and supported while they continue to be programme members. Monitoring software tracks the amount of health education curriculum consumed by the participants, participants are encouraged to continuously log weight, blood pressure and blood glucose levels on the platform. Participants who are not engaging with their educational curriculum can be sent personalised messages to encourage completion to facilitate health literacy. Some patients may require real time monitoring of weight, blood pressure, blood glucose, ketones, physical activity and dietary adherence.