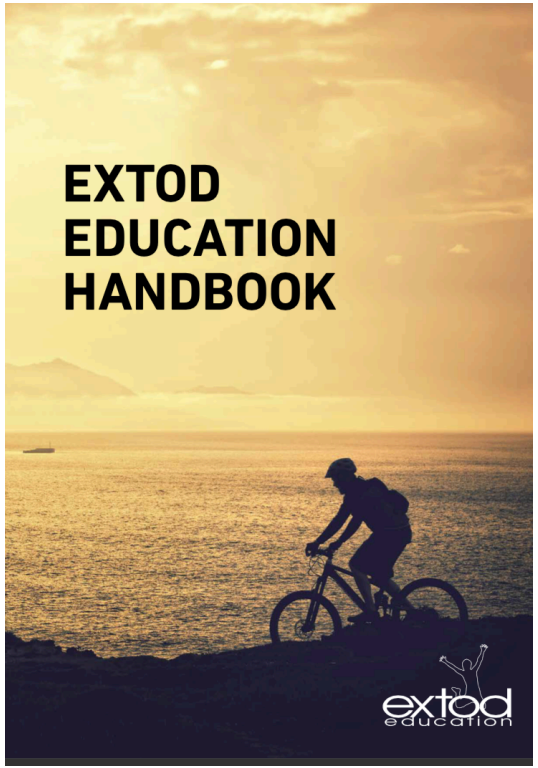
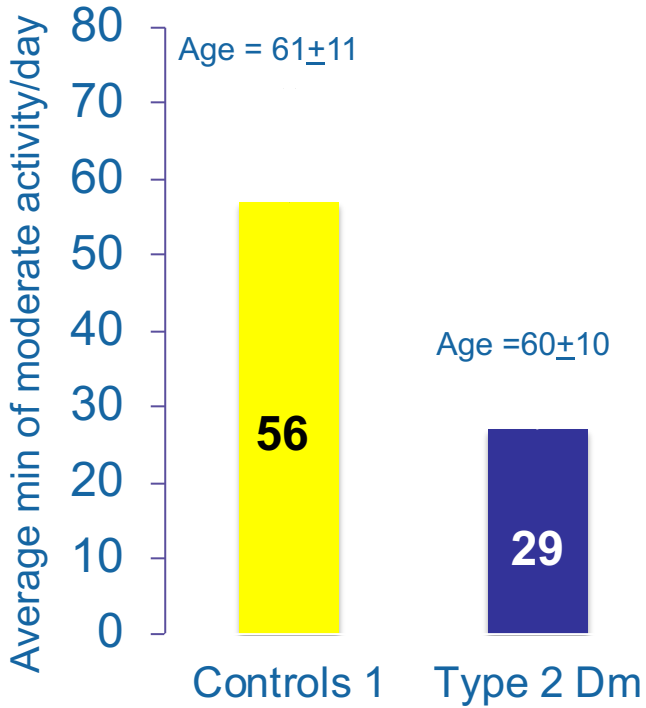
The EXTOD education programme



NIHR | National Institute for Health Research

extod education

Activity of Patients with diabetes



Rhys Matson et al 2019

Barriers to exercise in new onset adult T1D

Table 3 Barriers to increasing exercise cited by participants

External	Barrier (number of people mentioning barrier)
Medical	Hypoglycaemia (both actual and fear of) (9)
	Lack of knowledge/confidence in managing diabetes (6)
	Fatigue (4)
	Advice from healthcare professionals to stop exercising (4)
	Planning for diabetes (eg, checking blood glucose/preparing for hypoglycaemia) (4)
	Other physical health problems (eg, injuries) (3)
	Feeling overwhelmed by diagnosis. (1)
Time, work and environmental	Work commitments (9)
	Family and other time commitments (6)
	Availability and location of facilities (4)
	Cost (4)
	Weather/season (3)
	Lifestyle (2)
Internal Social and personal	Lack of fitness (3)
	Lack of motivation (2)
	Lack of enjoyment in certain activities (2)
	Laziness (1)
	Previous negative experience of exercise (1)
Psychological	Feeling uncomfortable exercising (eg, at a gym) (2)
	Feeling scared of exercising on own (2)
	Feeling daunted at prospect of starting (2)

Kennedy A et al BMJ Open 2018:8

extod

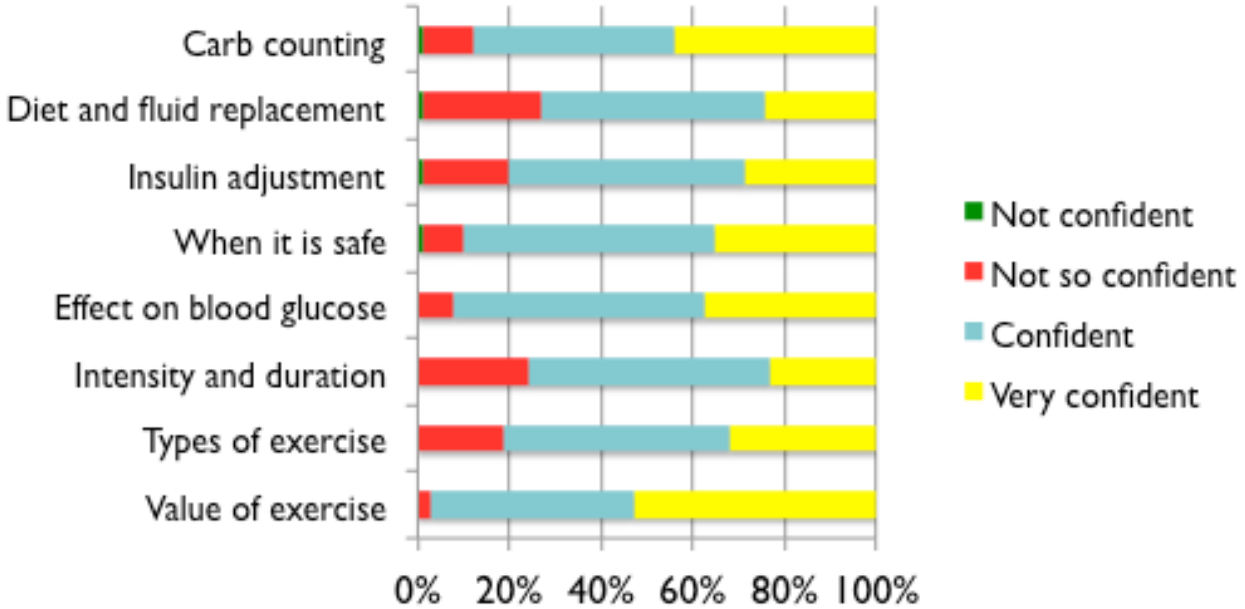
Diabetes specific barriers in adults with new-onset and established T1D

New onset T1D	Established T1D
• Hypoglycaemia (both actual and fear of) • Lack of knowledge/confidence in managing diabetes • Advice from healthcare professionals to stop exercising • Planning (e.g. checking blood glucose) • Feeling overwhelmed by diagnosis.	• Loss of control of diabetes • Lack of knowledge on the management of diabetes for exercise

Kennedy 2018, Lascar 2014

HCP confidence in giving advice

(162 responses. 44% Dieticians, 30% Drs, 25% nurses)



85% of HCPs reported they were very confident or confident at providing exercise education on all key topics

L Rich et al, Poster presentation at IDF 2015.

Knowledge levels of HCPs

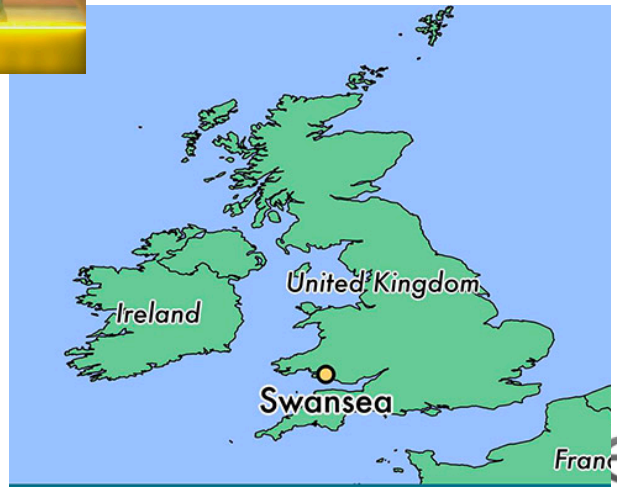
Average scores for each domain (the number of questions in each domain)	Correct responses	
	n (N)	%
General knowledge (4)	151 (648)	23
Action depending on blood glucose (8)	839 (1296)	65
Adjustment of rapid acting insulin (6)	459 (972)	47
Adjustment to basal insulin (6)	334 (972)	34
Risk of hypoglycaemia (2)	42 (324)	13
Insulin injection sites (2)	207 (324)	64
Food and drink consumption (3)	334 (486)	69
Treatment of hypoglycaemia (1)	98 (162)	60

Knowledge levels were poor

89% of respondents wanted more formal education for managing T1D for exercise. L Rich et al, Poster presentation at IDF 2015.

EXTOD 101

Aim was to set world record
for most people
with Type 1 diabetes
to run a half marathon



Aims of study

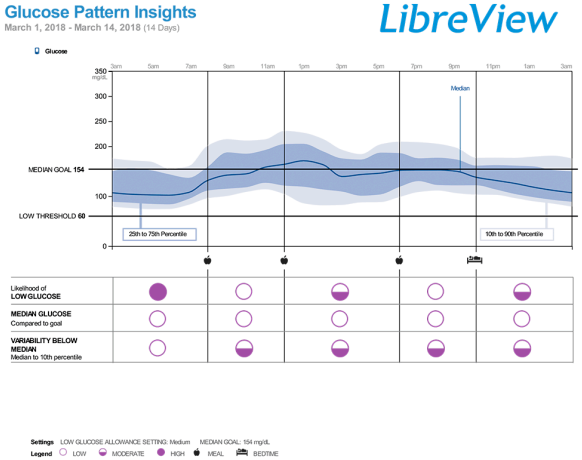
- To record what happens with blood glucose in patients with T1D training for and competing in a half marathon
- To document what strategies they used to control glucose during training and during the race
- To see if all this could be done remotely

Methods

Glucose control

8 weeks before, day of race

2 weeks after



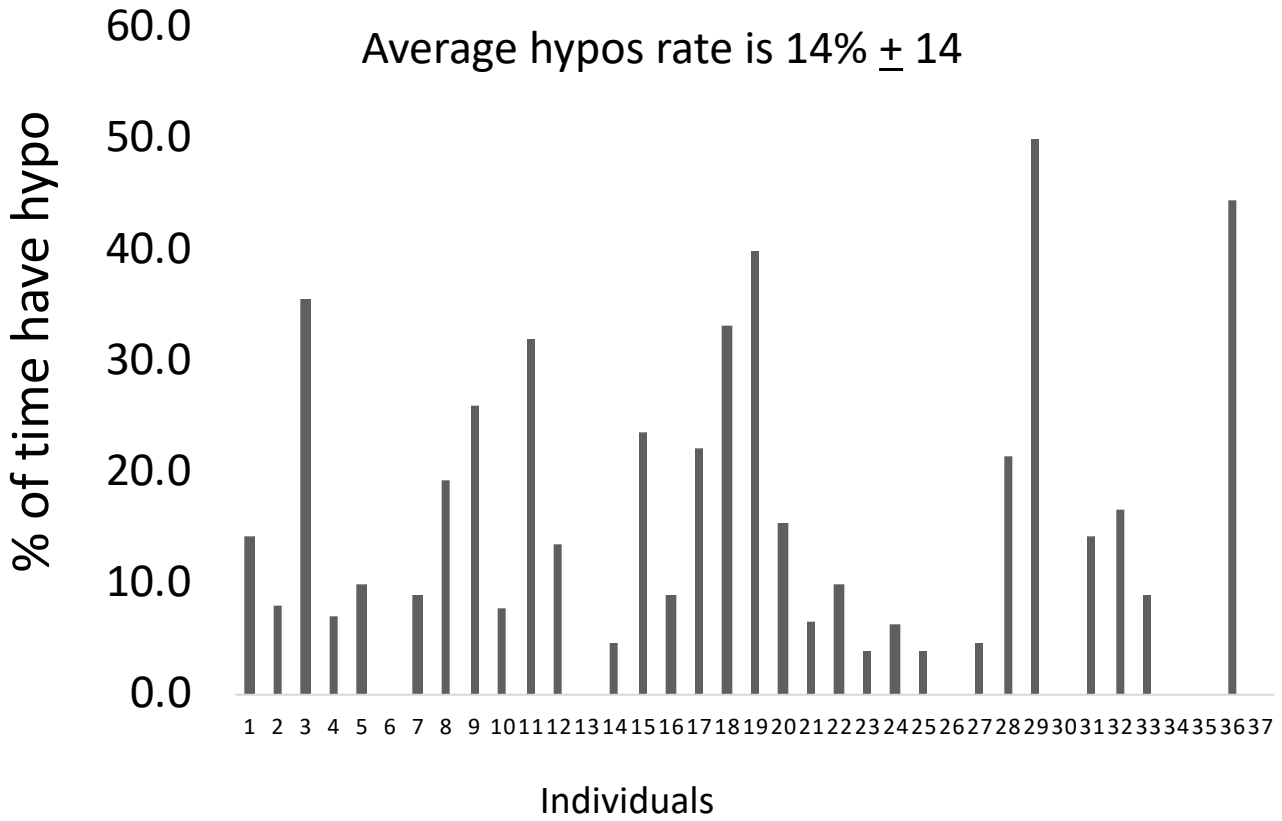
Demographics

Characteristic	
Age (years)	44 ± 12
Sex (F:M)	21:16
Treatment (Pumps: MDI)	15:22
Diabetes Duration (years)	22 ± 5
BMI	23.2 ± 4.7
HbA1c (%)	7.3 ± 0.6

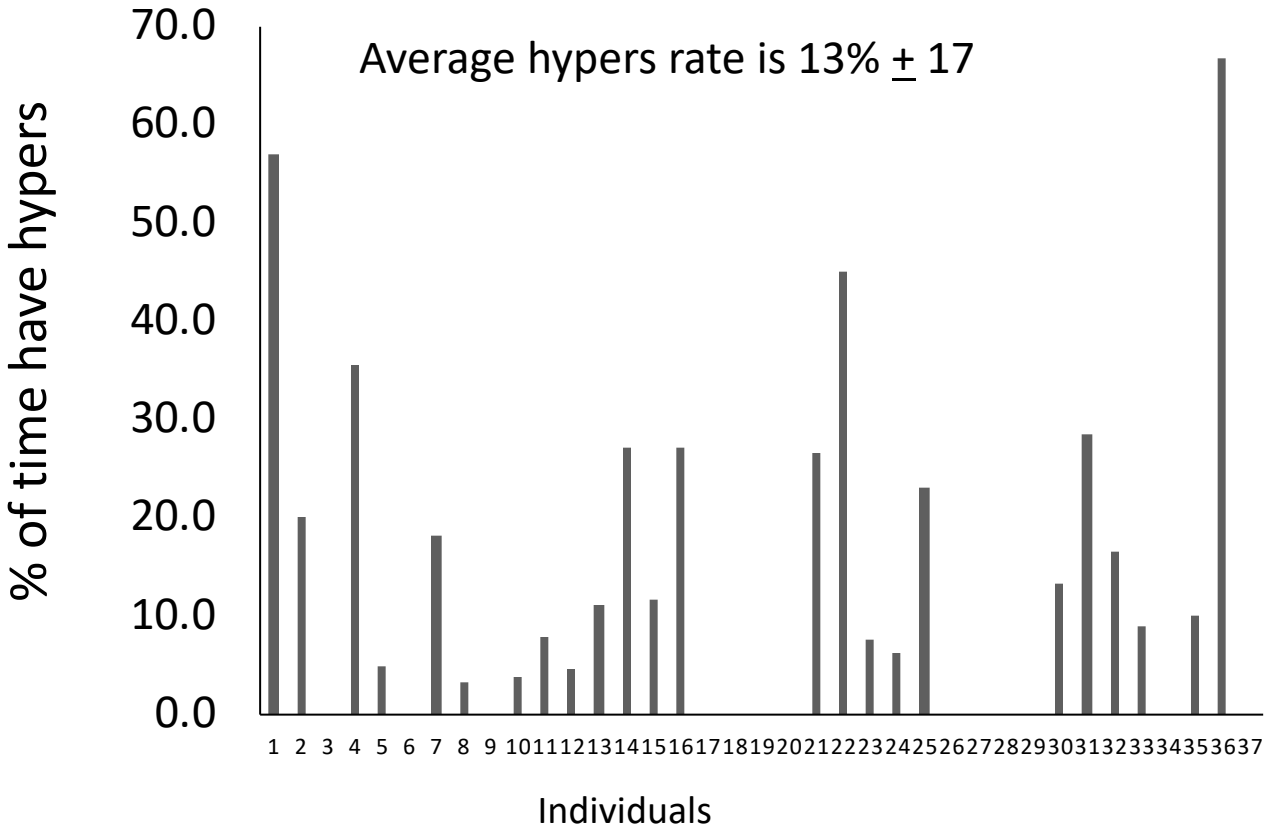
Training before

Number of days recorded	36 ± 9
Number days trained	16 ± 2 (44%)
% of training days that was run	71 ± 23
Intensity (borg)	14 ± 1.4
Length (minutes)	70 ± 33
Average glucose before	183 ± 49
Average glucose after	143 ± 40

Number of Hypos during exercise



Number of Hypers during exercise



Summary 1 - training

- Hypo and Hyperglycaemia are common when running in people with T1D training for a half marathon

- 27% of the time the patient will have a problem with one of these

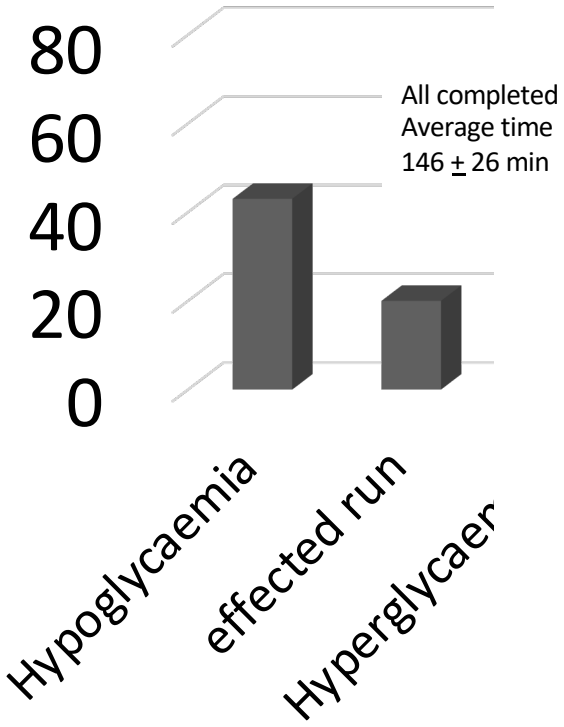
Race day

Night before the race

Took extra carbohydrate	54% (19)
Reduced background insulin	11% (4)
Number who had hypo	14% (5)

No one needed help to manage

During the race



After the race – evening

Snack before bed	37% (13)
Reduced background insulin	34% (12)
Hypo over night	17% (6)

One person needed help with hypo

Conclusion

- Patients have a lot of problems with hypos and hyperglycaemia when training for and completing a half marathon.

- Research is needed as to how best to support them.

Overarching aim of the study

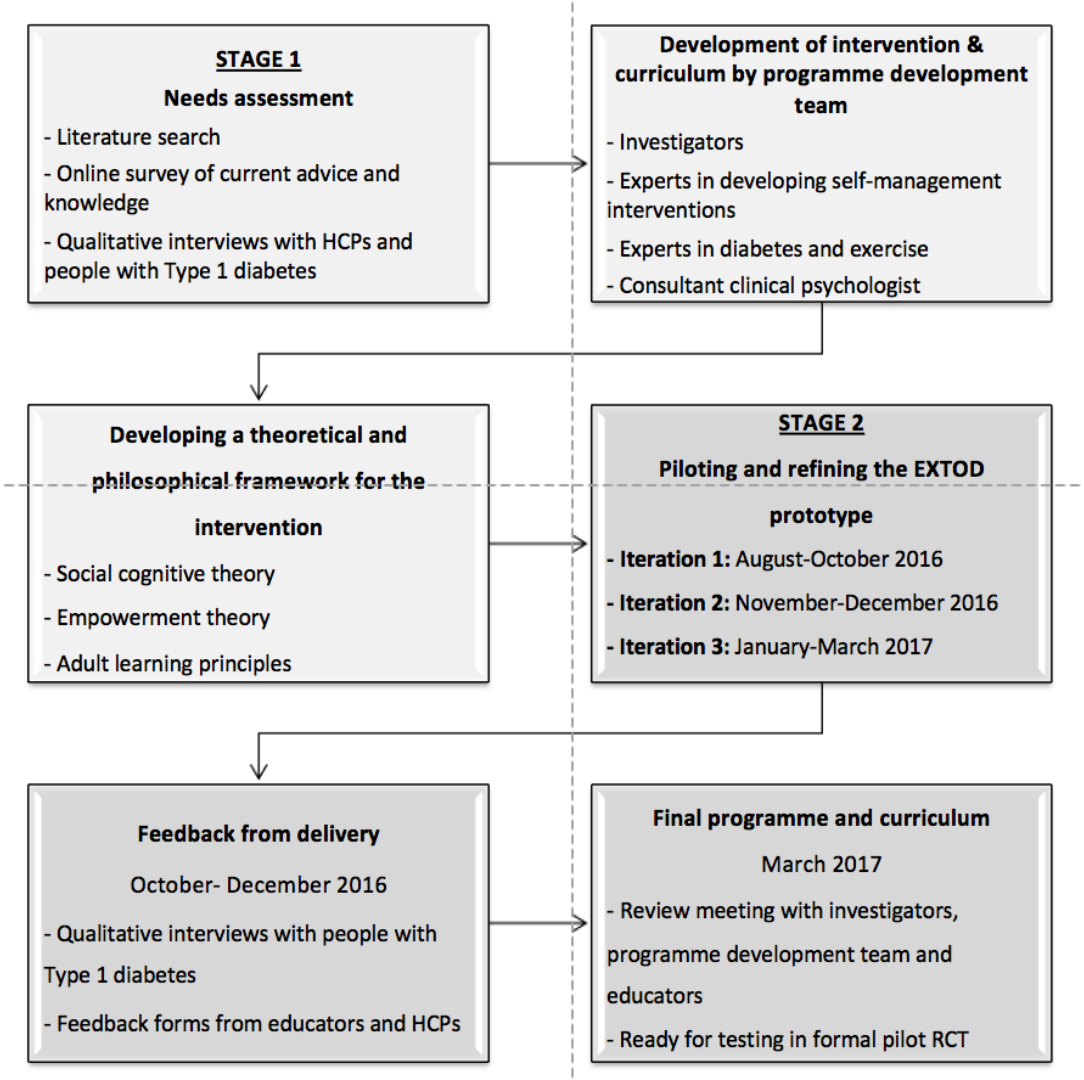
To develop and pilot an education programme for such people (with accompanying training for HCPs to deliver this programme) to guide insulin and carbohydrate adjustment for safe exercise.

The results will be used to design a definitive trial to assess the effect of this education programme on exercise levels in people with T1DM.

extod education

Phase 1 - aim

The primary aim is to develop an education programme for patients with T1DM and accompanying training for HCPs who regularly work with patients with T1DM to guide insulin and carbohydrate adjustment for safe exercise.


STAGE 1
Needs assessment
- Literature search
- Online survey of current advice and knowledge
- Qualitative interviews with HCPs and people with Type 1 diabetes
Development of intervention & curriculum by programme development team
- Investigators
- Experts in developing self-management interventions
- Experts in diabetes and exercise
- Consultant clinical psychologist
Developing a theoretical and philosophical framework for the intervention
- Social cognitive theory
- Empowerment theory
- Adult learning principles
STAGE 2
Piloting and refining the EXTOD prototype
- Iteration 1: August-October 2016
- Iteration 2: November-December 2016
- Iteration 3: January-March 2017
Feedback from delivery
October- December 2016
- Qualitative interviews with people with Type 1 diabetes
- Feedback forms from educators and HCPs
Final programme and curriculum
March 2017
- Review meeting with investigators, programme development team and educators
- Ready for testing in formal pilot RCT

Phase 1 – needs assessment

TABLE 1 | Patient participants.

Study ID	Time since diagnosis (years)	Exercise regime (Sessions per week)
SOUTH WEST (SW)		
P1	3.5	Gym x2, Karate x2
P2	20	Dance x4, Perform x1
P3	5	Hockey training x4, Play at the weekend
P4	3	Football x1, Cycle commute and run regularly
P5	50+	Gym x2, Keep fit class x1
P6	5.5	Horse riding x7 (Competes on weekends)
P7	3	Gym x3
P8	4	Cycling x2, Gym x1
WEST MIDLANDS (WM)		
P9	17.5	Gardening, Aikido x3
P10	2	Swim x1, Keep fit x1
P11	56	Gardening, Walking, Infrequent cycling
P12	36	Walking short distances x7
P13	6	Badminton x3
P14	6	Squash x1, Cycling x5

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Phase 1 – needs assessment

TABLE 2 | Staff participants.

Study ID	Job title	Time in post (years)	Exercise education provided
SOUTH WEST			
HCP1	Diabetes dietician	21	Teach on carbohydrate counting course (plus 4 h a week research)
HCP2	Diabetes dietician	8	Teaches on carbohydrate counting course, specialist interest in sport
HCP3	Diabetes dietician		Pediatrician (previously adult) Teaches on carbohydrate counting course
HCP4	Diabetes specialist nurse	6	Teaches on carbohydrate counting course
HCP5	Diabetes specialist nurse	12	1 day a week "pumps adviser"
HCP 6	Consultant in diabetes endocrinology, acute and general internal medicine	13	Proactive enquiry around exercise during consultation. Advises on range of exercise and activity
HCP 7	Consultant diabetes endocrinologist, and the clinical lead for patient specialities	8	Advises patients on recreational exercise and events such as marathons
WEST MIDLANDS			
HCP8	Speciality Doctor	8	Educates patients on exercise in response to their enquiries
HCP9	Diabetes dietician	2	Deliver the exercise section of the carbohydrate counting course.
HCP10	Specialist dietician	4	Teaches exercise as part of education programmes for both Type 1 and Type 2 diabetes.
HCP11	Diabetes specialist nurse	15	Teaches on carbohydrate counting course
HCP12	Diabetes specialist nurse	15	Teaches on carbohydrate counting course
HCP13	Diabetes specialist nurse	14.5	Teaches on carbohydrate counting course

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Phase 1 – needs assessment

TABLE 3 | Influences on the successful delivery of exercise education: themes and sub-themes.

Theme	Sub theme 1	Sub theme 2
1.0 Exercise regime	1.1 Type of exercise	Predictable intensity Anaerobic exercise Specialized sport
	1.2 Patterns of exercise	Routine vs. sporadic
	1.3 Intensity	Competitive vs. non-competitive
2.0 Patient engagement	2.1 Patient preference	Priority of exercise
	2.2 Self-management	Monitoring Carbohydrate counting
	2.3 Health Literacy	Understanding advice
3.0 Organizational factors	3.1 Staff training	Limited knowledge of the effects of exercise Deskilling
	3.2 Capacity	Limited access to education packages Limited access to specialist providers Length of consultation
	3.3 Coherence of care	Consistency of message Continuity of care
4.0 Existing education strategies	4.1 Structured education package	Criteria for inclusion
	4.2 Format and content	Patient stories Generic written information

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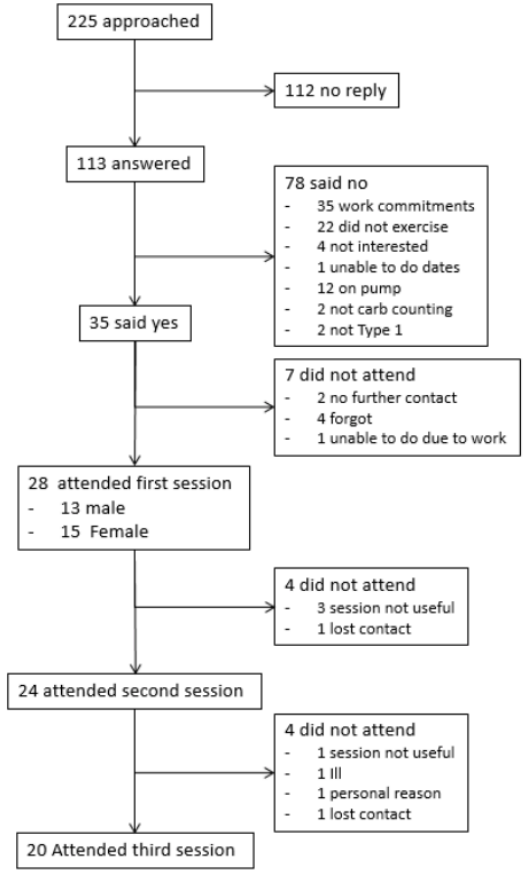
Phase 1 - Theoretical framework

Problem behaviours	Potential behavioural outcome (Target behaviours)	Theory	Mapping to behavioural taxonomy (24, 25)	Sample activity within EXTOD programme
Low levels of confidence to engage in physical activity of choice	High levels of confidence to engage in physical activity of choice	**Self-efficacy (26, 27)** • **Mastery** (previous successful attempts of the behaviour) • **Modelling** (observing others like oneself engaging in the behaviour) • **Verbal persuasion** (talking through the process of change, planning for obstacles, success) • **Emotions management**	• Focus on past successes • Self-monitoring of behaviour outcomes and consequences • Instruction on how to perform behaviour • Graded tasks • Behavioural experiments • Credible source • Habit reversal • Review behavioural goal • Social comparison	**Sharing stories sessions:** • Eliciting what has gone well in terms of behaviour change, problem solving around challenges and observing others successes and challenges • Discussion of barriers to change • Acknowledgement of feelings and emotions **Next steps and future planning sessions** • Action planning • Problem solving • Setting short term goals
Not measuring blood glucose (BG) at appropriate times, before, during and after exercise.	Taking blood glucose (BG) measurement at the times appropriate to exercise.	Social Cognitive theory **(16)**	• Behavioural substitution • Habit reversal • Self-beliefs	Exploration of barriers and enablers to BG monitoring at specific times Facilitation of individualised problem solving strategies.
Not carrying hypo treatments and/or having incorrect hypo treatments	Deciding on appropriate hypo treatment and taking it to all exercise activities.	Social Cognitive theory **(16)**	• Behavioural substitution • Habit reversal	Supporting the exploration of barriers and enablers to carrying the correct hypo treatment Facilitation of individualised problem solving strategies

Phase 1 - Theoretical framework

Problem behaviours	Potential behavioural outcome (Target behaviours)	Theory	Mapping to behavioural taxonomy (24, 25)	Sample activity within EXTOD programme
Continuing to exercise following a low/high BG reading.	Taking necessary precautions if BG readings are outside of safe zone – delaying exercise or making corrections and retesting before commencing exercise.	Social cognitive theory **(16)**	• Behavioural substitution • Habit reversal	Supporting the exploration of barriers and enablers to exercising when BG are too high or too low Facilitation of individualised problem solving strategies
Not considering the longer-term influence of exercise on BG levels and therefore not taking steps to avoid hypos up to 14 hours after exercise.	Having a plan to ensure BG does not drop too low – meals, snacks, bedtime snack to protect against hypo.	Social cognitive theory **(16)**	• Problem solving • Goal setting • action planning • Anticipated regret	Supporting the exploration of barriers and enablers to longer term BG monitoring Facilitation of individualised problem solving strategies

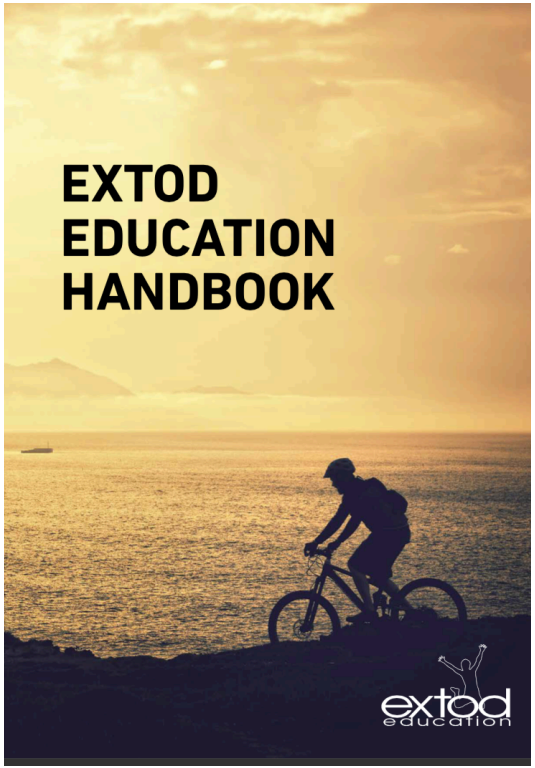
Testing and refining

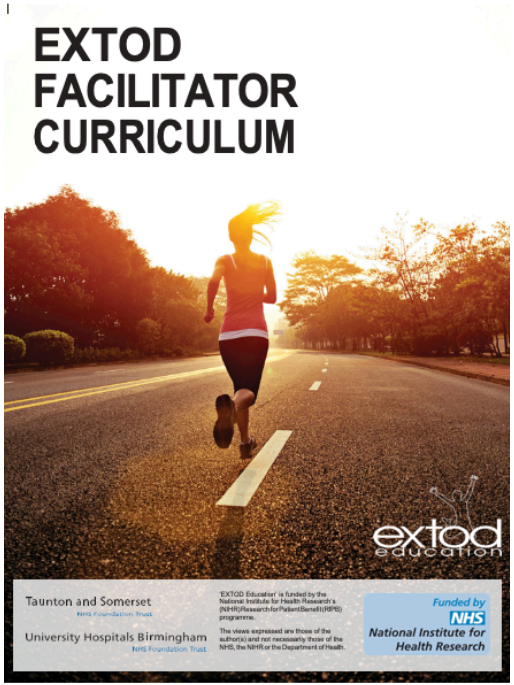


56% of those who said yes completed the course
71% of those who attended the first session completed the course

Characteristics of participants attending EXTOD Education course		
Taunton		
Women	12	18-64
Men	7	24-68
Birmingham		
Women	3	52-69
Men	6	28-60
Total		
Women	15	19-69
Men	13	24-68

Phase 1 – final programme





Litchfield 2019
Narendran 2019

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Session 1	Session 2	Session 3
Welcome (10 mins)	Welcome back (5 mins)	Welcome back (5 mins)
Where are you now? (40 mins)	Sharing stories (30 mins)	Sharing stories (30 mins)
Understanding your mechanics (55 mins)	Mechanics 2 (30 mins)	Advanced strategies (55 mins)
Staying safe (25min)	Fuelling for exercise (60 minutes)	
Strategies before and during (55 mins)	Strategies after (30 mins)	
Next steps (20 mins)	Next steps (20 mins)	Future planning (30 mins)
TOTAL – 3 Hours 25 mins	TOTAL – 2 Hours 50 mins	TOTAL – 2 Hours

Week 0 | 1 week later | 4 weeks later

Phase 2 - aims

- Determine the number of people with T1DM who would be eligible to participate in an RCT of such an education programme.
- Determine the proportion of these people who would be willing to participate in this trial (that is, recruitment rate), and their characteristics.
- Define the rates of adherence to the intervention and participant drop-out from the study, particularly to determine whether retention differs between the usual care and intervention arms.
- Generate estimates of statistical properties of potential outcome measures (e.g. variances) that are needed for sample size calculations for the definitive trial. The outcomes measures that will be assessed are exercise, fear of hypoglycaemia, frequency of hypoglycaemia, self-reported barriers to exercise, and well-being.

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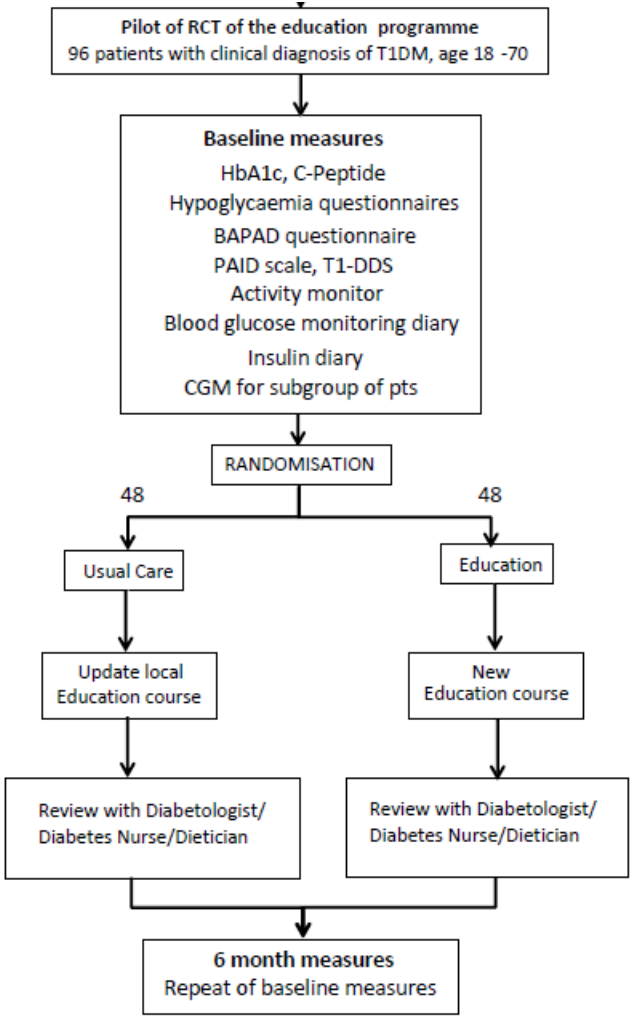
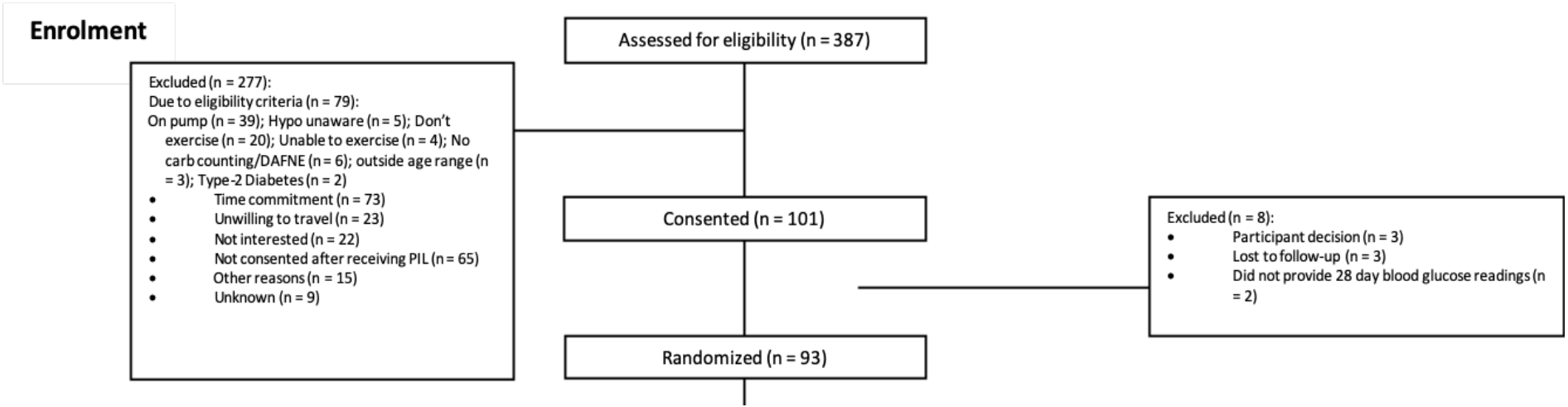

Pilot of RCT of the education programme
96 patients with clinical diagnosis of T1DM, age 18 -70
Baseline measures
HbA1c, C-Peptide
Hypoglycaemia questionnaires
BAPAD questionnaire
PAID scale, T1-DDS
Activity monitor
Blood glucose monitoring diary
Insulin diary
CGM for subgroup of pts
RANDOMISATION
48
48
Usual Care
Education
Update local Education course
New Education course
Review with Diabetologist/ Diabetes Nurse/Dietician
Review with Diabetologist/ Diabetes Nurse/Dietician
6 month measures
Repeat of baseline measures

Consort


Enrolment
Assessed for eligibility (n = 387)
Excluded (n = 277):
Due to eligibility criteria (n = 79):
On pump (n = 39); Hypo unaware (n = 5); Don't exercise (n = 20); Unable to exercise (n = 4); No carb counting/DAFNE (n = 6); outside age range (n = 3); Type-2 Diabetes (n = 2)
Time commitment (n = 73)
Unwilling to travel (n = 23)
Not interested (n = 22)
Not consented after receiving PIL (n = 65)
Other reasons (n = 15)
Unknown (n = 9)
Consented (n = 101)
Excluded (n = 8):
Participant decision (n = 3)
Lost to follow-up (n = 3)
Did not provide 28 day blood glucose readings (n = 2)
Randomized (n = 93)

Number eligible

	Birmingham			Taunton			Overall		
No of participants approached	163			223			387		
	N	%	95% cl	N	%	95% cl	N	%	95% cl
No of participants eligible to be randomised	137	0.84	0.76 to 0.89	171	0.76	0.70 to 0.82	308	0.80	0.75 to 0.983

80% of participants approached are eligible to be randomised

extod education

Number willing to enter study

	Birmingham			Taunton			Overall		
No of participants approached	137			171			308		
	N	%	95% cl	N	%	95% cl	N	%	95% cl
Number and proportion (of those eligible) of participants randomised	42	0.31	0.23 to 0.39	51	0.30	0.23 to 0.37	93	0.30	0.25 to 0.36

30% of participants of eligible patient were willing to be randomized

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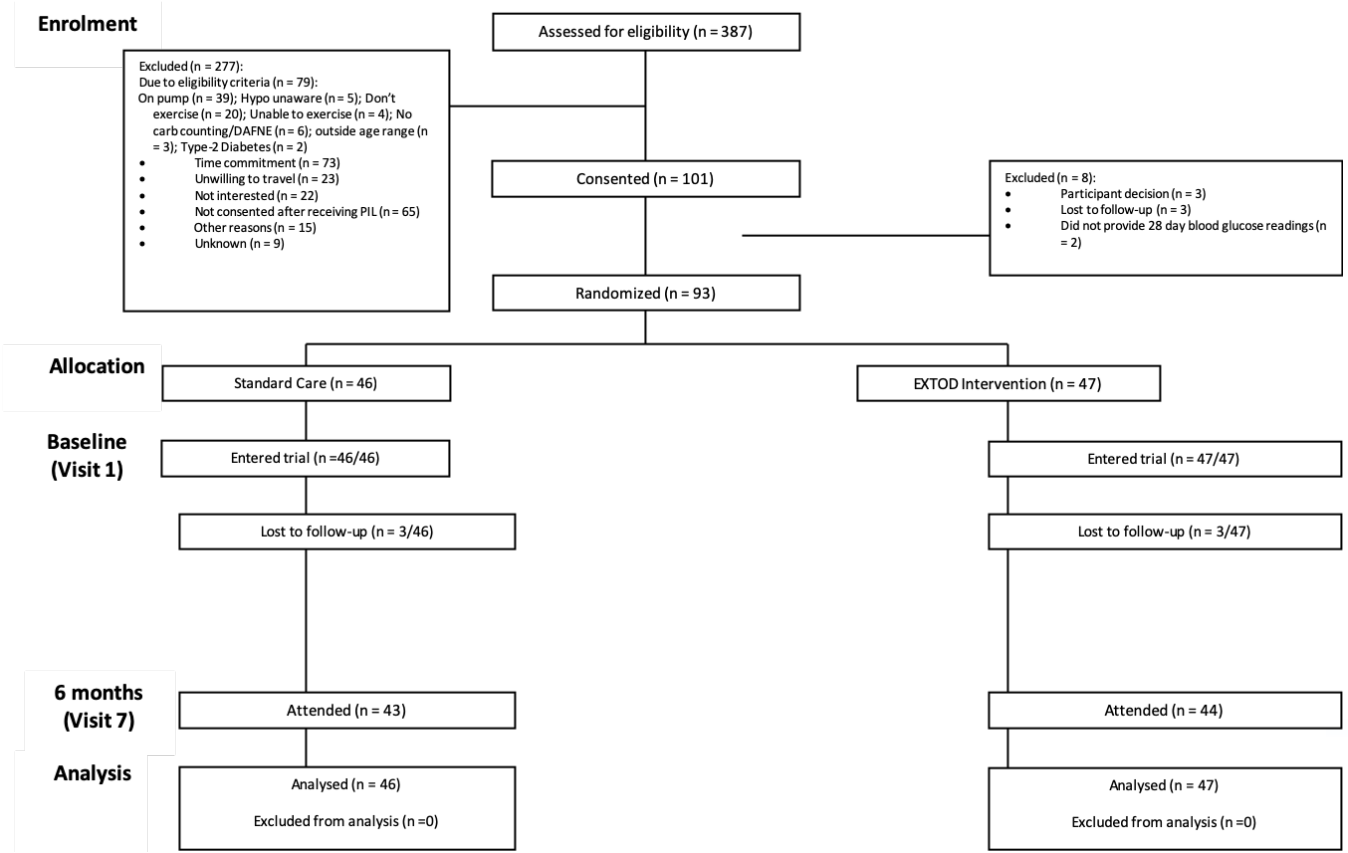
Consort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Unknown (n = 9)
Consented (n = 101)
Excluded (n = 8):
Participant decision (n = 3)
Lost to follow-up (n = 3)
Did not provide 28 day blood glucose readings (n = 2)
Randomized (n = 93)
Allocation
Standard Care (n = 46)
EXTOD Intervention (n = 47)
Baseline (Visit 1)
Entered trial (n =46/46)
Entered trial (n = 47/47)
Lost to follow-up (n = 3/46)
Lost to follow-up (n = 3/47)
6 months (Visit 7)
Attended (n = 43)
Attended (n = 44)
Analysis
Analysed (n = 46)
Excluded from analysis (n =0)
Analysed (n = 47)
Excluded from analysis (n =0)

Participant characteristics - 1

	Usual Care (n=46)	Intervention (n=47)	Overall (n=93)
Age (years)	47 ± 12	46 ± 14	46 ± 13
Gender (M:F)	27:19	29:18	56:37
Height (cm)	172 ± 9	174 ± 9	173 ± 9
Weight (kg)	80.0 ± 14.3	76.1 ± 13.6	78.1 ± 14.0
Waist circumference (cm)	93 ± 13	89 ± 13	91 ± 13
Body Fat content (BPM)	24.3 ± 13.5	23.2 ± 11.3	23.8 ± 12.4
Systolic BP (mmhg)	127 ± 15	126 ± 15	126 ± 14
Diastolic BP (mmhg)	78 ± 8	77 ± 7	77 ± 8
Heart rate (bpm)	71 ± 11	70 ± 9	70 ± 10
HbA1c (mmol/mol)	63 ± 12	61 ± 11	62 ± 11

Participant characteristics - 2

	Usual Care (n=46)	Intervention (n=47)	Overall (n=93)
Duration Diabetes (years)	18.2 ± 13.7	17.6 ± 13.9	17.9 ± 13.7
Number (%) retinopathy	8 (17.4%)	6 (12.8%)	14 (15.1%)
Number (%) neuropathy	2 (4.3%)	0 (0%)	2 (2.2%)
Number (%) Nephropathy	3 (6.5%)	4 (8.5%)	7 (7.5%)
Number (%) Hypertension	7 (15.2%)	14 (29.8%)	21 (22.6%)
Number (%) Hyperlipideamia	17 (37%)	20 (42.5%)	37 (39.5%)
Number (%) hypothyroid	7 (15.2%)	6 (12.8%)	13 (14.0%)
Number (%) PVD	1 (2.2%)	1 (2.1%)	2 (2.1 %)
Number (%) IHD	1 (2.2%)	2(4.3%)	3 (3.2%)

Phase 2 – adherence rates - 1

	Usual Care (n=46)			Intervention (n=47)			Overall (n=93)		
	N	%	95% cl	N	%	95% cl	N	%	95% cl
Number and proportion (of those randomised) of participants assessed at 6 month follow-up visit	43	0.93	0.82 to 0.99	44	0.94	0.82 to 0.99	87	0.94	0.86 to 0.98

Overall retention rate 94%

No difference in retention rate between usual care and intervention

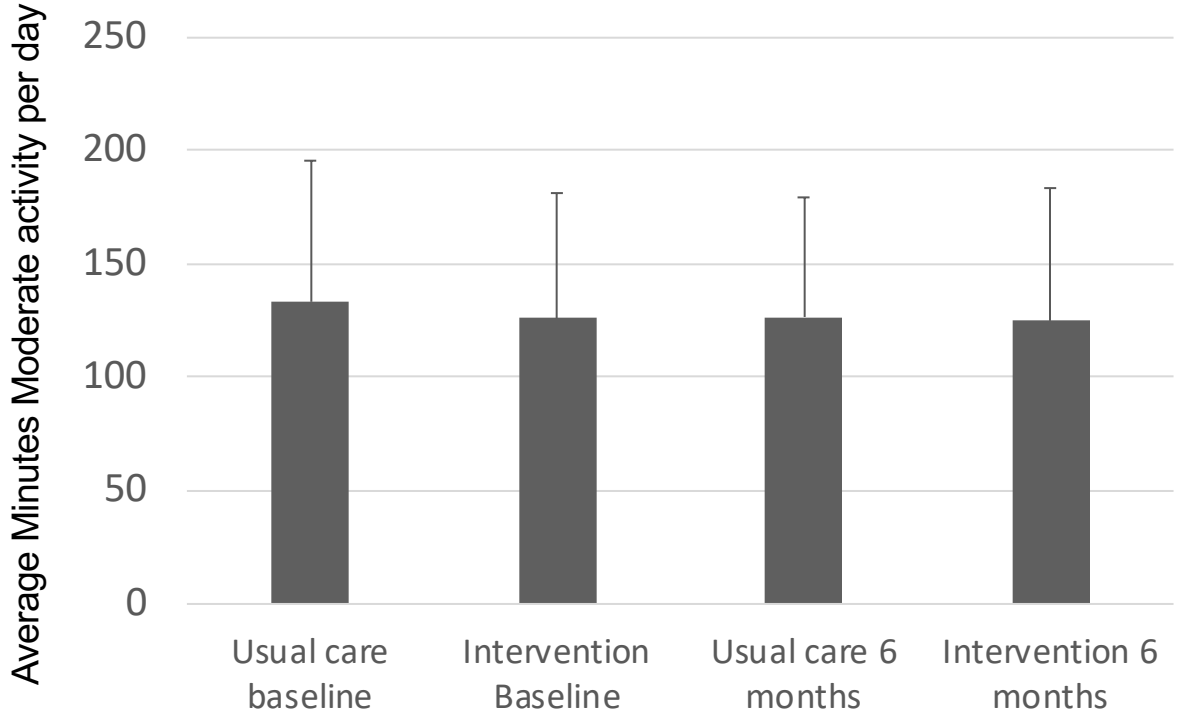
extod education

Summary 1

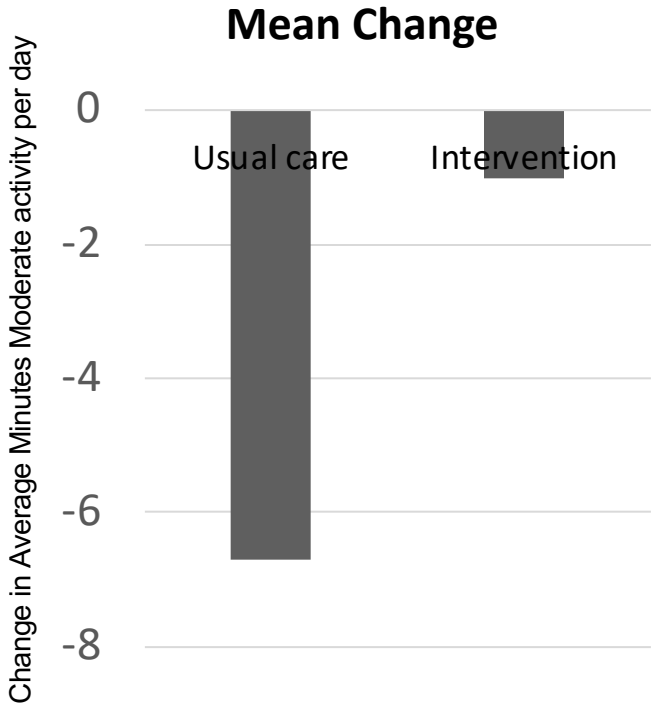
- Eligibility to the study is good (80%).
- Uptake is very good (30% most Type studies 8-10%)
- Adherence to treatment is good and no different between the 2 arms

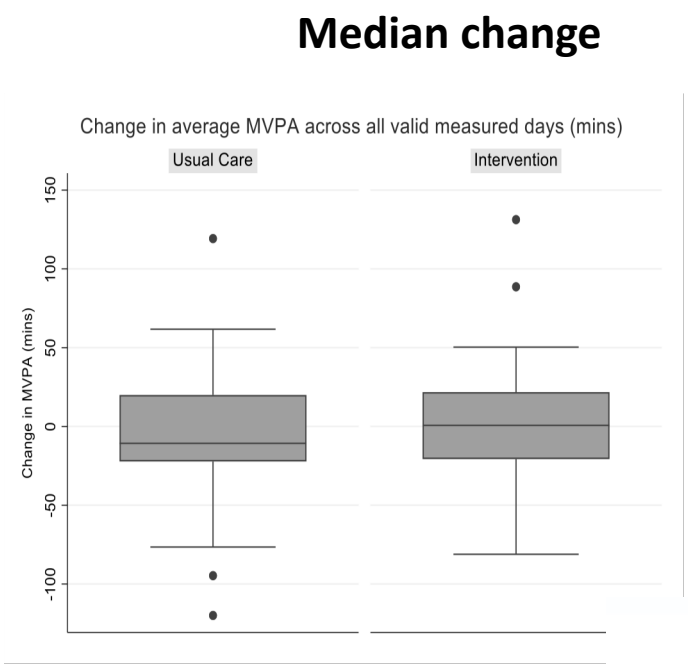
extod education

Activity at each time point

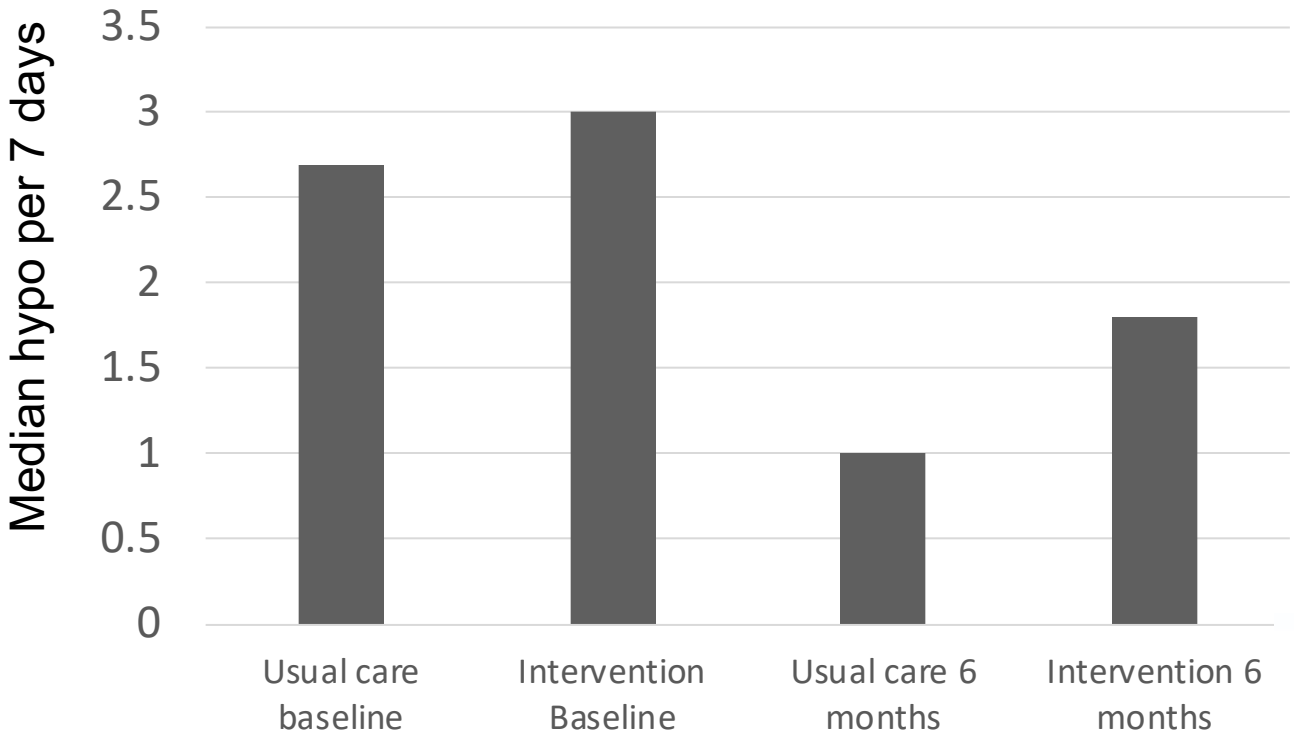


Activity – change over 6 months





Hypos at each time point



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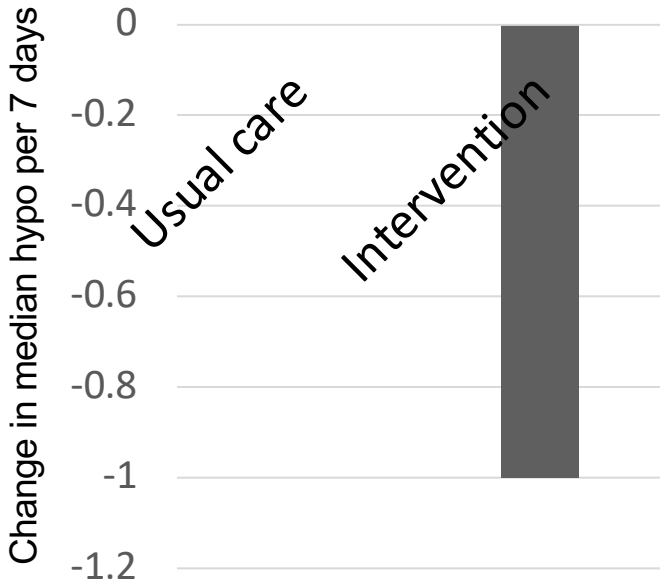
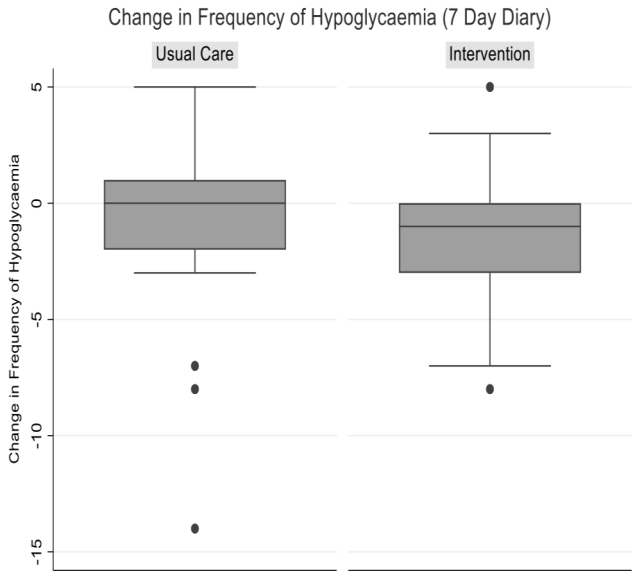
Hypos– change over 6 months

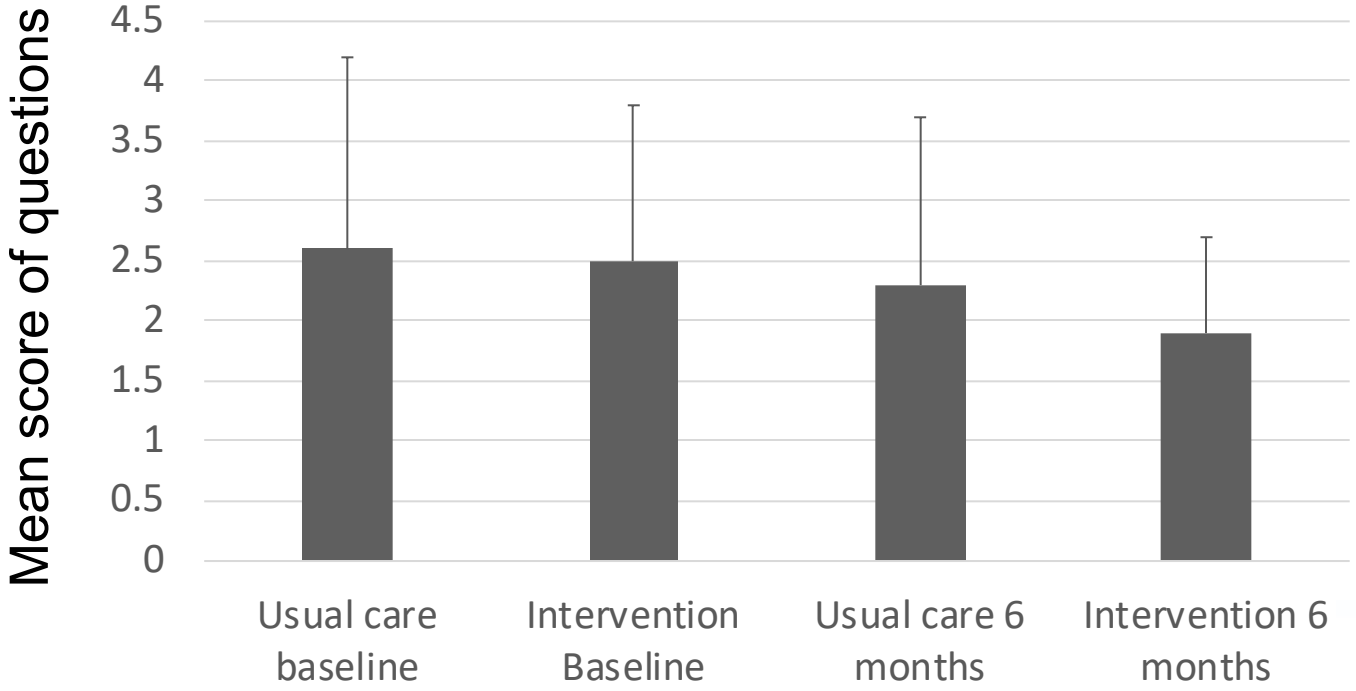
Mean



Median



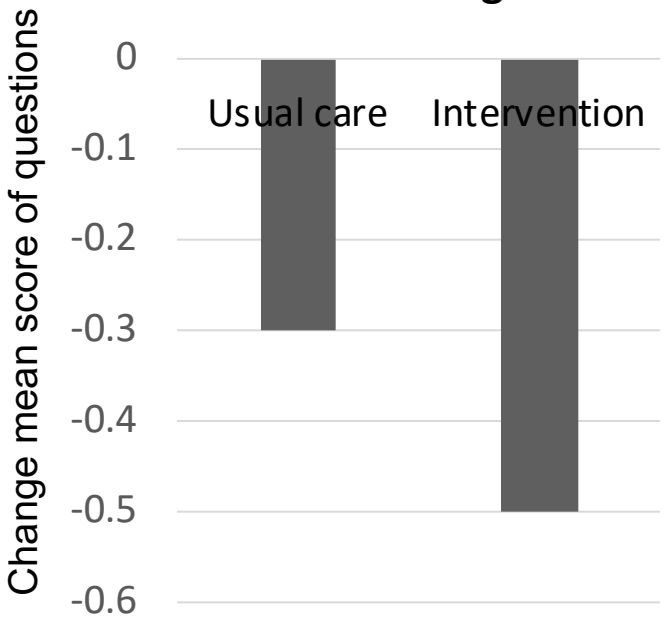
BAPAD- 1 at each time point



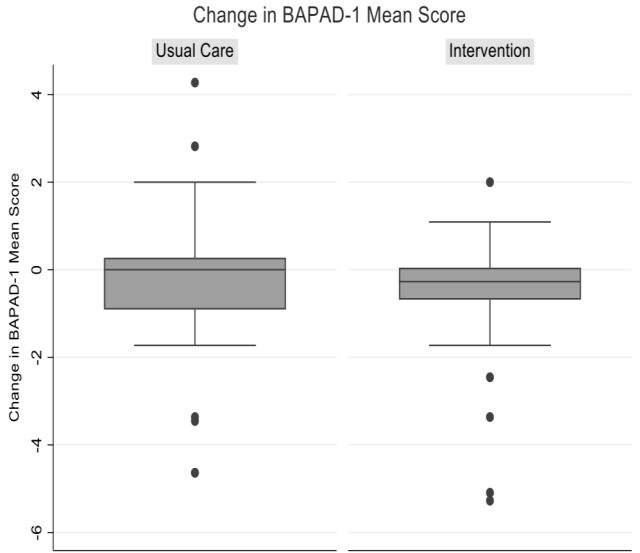
extod education

BAPAD-1– change over 6 months

Mean change

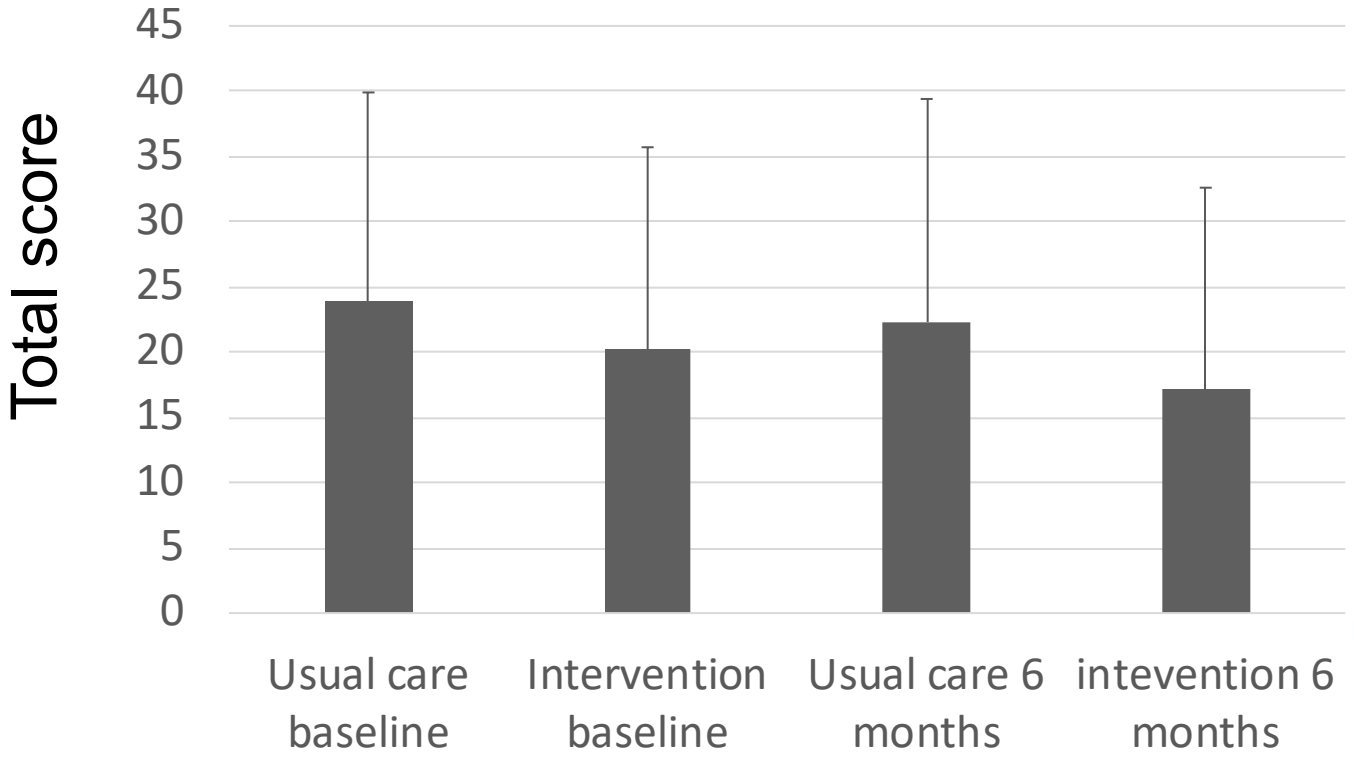


Median change



extod education

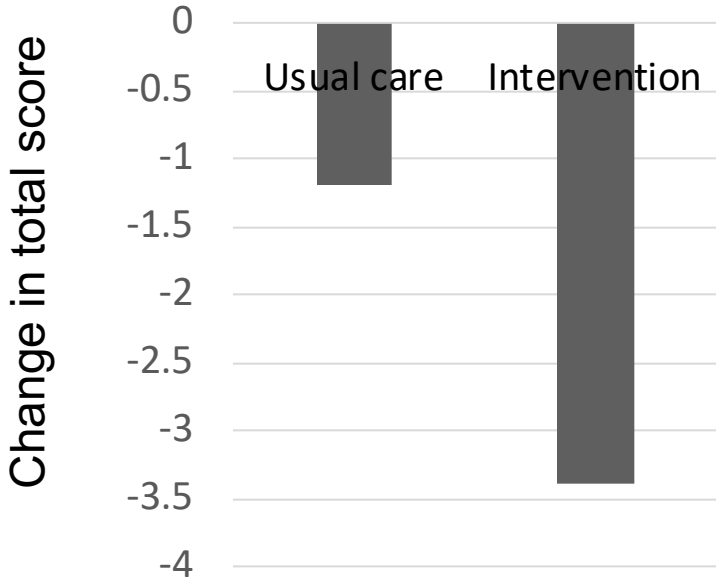
PAID at each time point



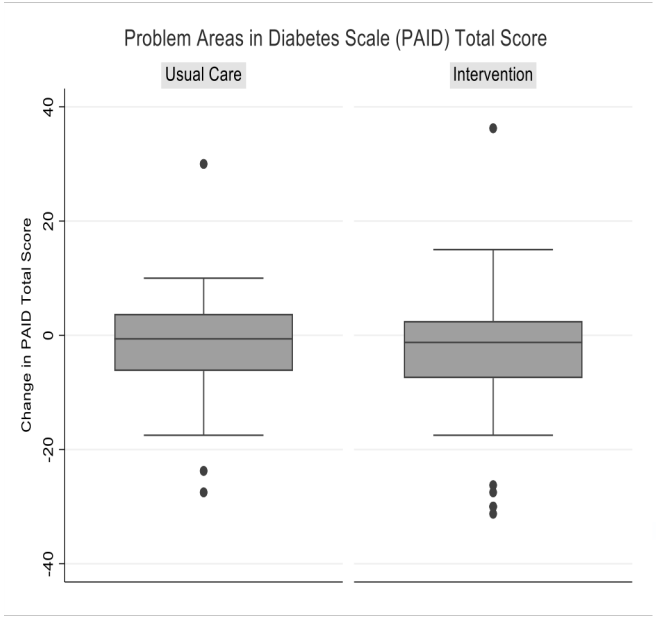
extod education

PAID score – change over 6 months

Mean change

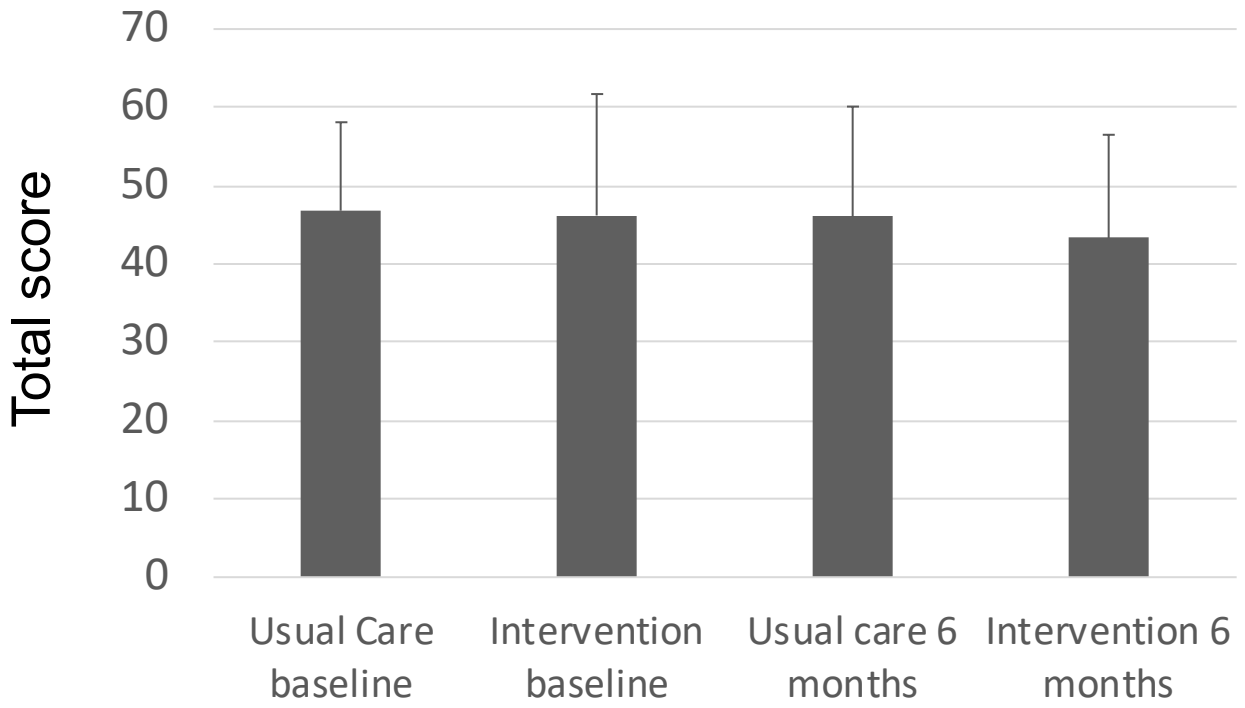


Median change



extod education

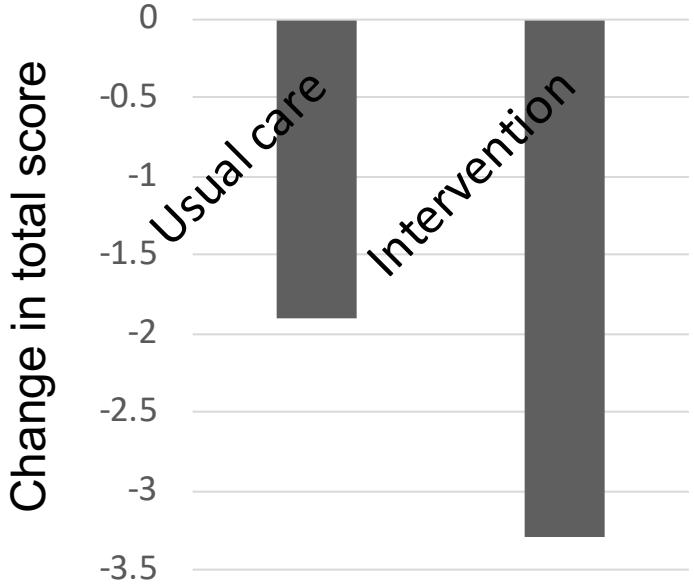
T1DSS at each time point



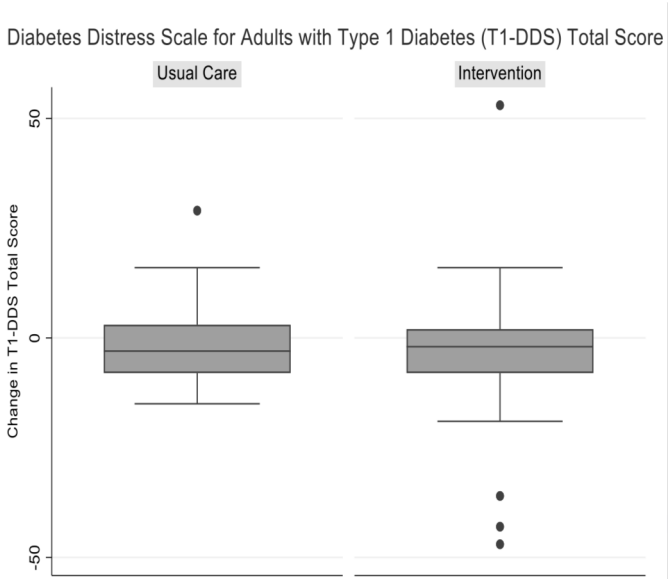
extod education

T1DSS Score – change over 6 months

Mean change



Median change



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Conclusion

There is a suggestion that the programme

- Helps to reduce hypoglycaemia
- Improves well being

Further analysis of glucose variability around exercise is ongoing

A full trial is needed

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