Perioperative Glycaemic Control in Pancreas Transplant Recipients: A Feasibility Study

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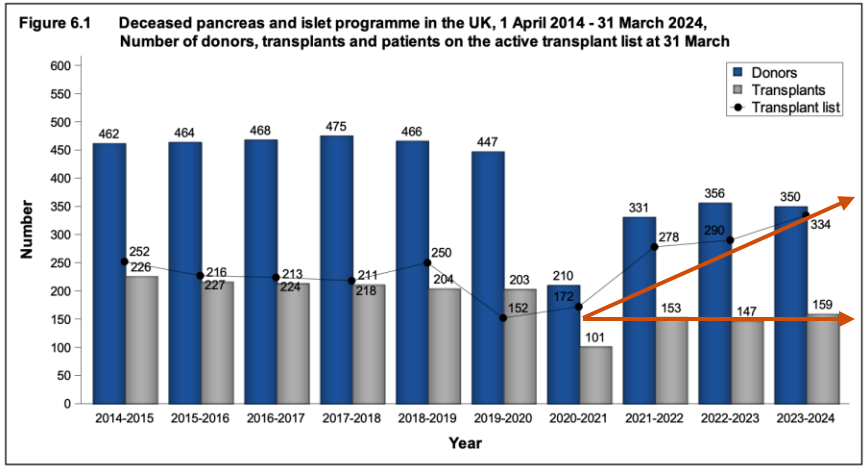
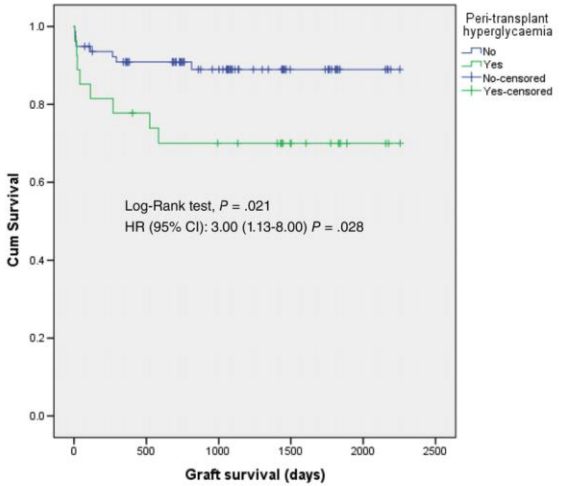
The problem



What we have shown



What we don't know

hyperglycaemia → early graft failure?

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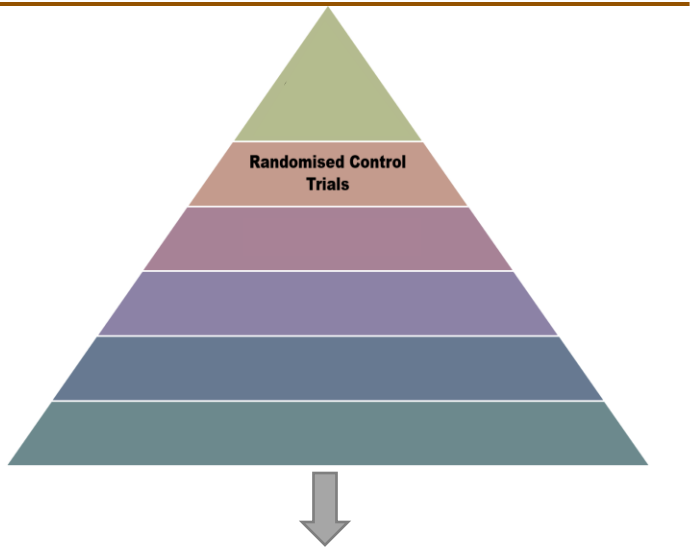
The Solution

Tight glycaemic control (<7mmol/L)

Standard care



Graft survival

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The Trial

Feasibility trial: Single arm study of the intervention arm

Full trial: Randomised controlled trial of the intervention versus standard care

Inclusion:
- Type-1 diabetics listed for solid-organ pancreas transplantation

Exclusion:
- Previous pancreas transplant, age <18, inability to provide informed consent

Feasibility trial sample size: 20 participants
- Enables us to detect 87% recruitment with a 95% binomial CI of 66.4-97.2%.

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The Intervention

Variable rate insulin infusion:
- Study specific protocol adapted from Portland
- 4.0 – 6.9mmol/L
- 5 days postoperatively

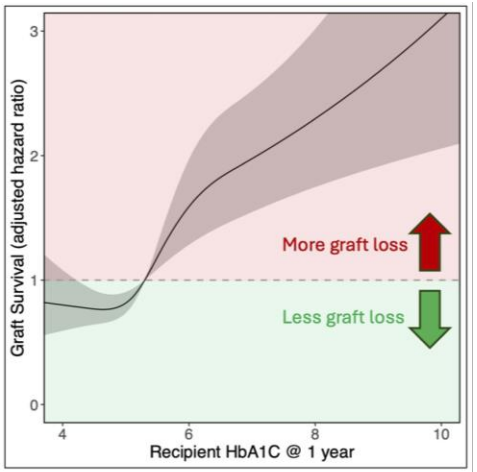
Safety Features:
- Dexcom 7 CGM
- Discontinued on step down to ward
- Central blood samples
- Escalation of increasing insulin requirement

Primary Outcomes

	Recruitment	Completeness	Safety	Adherence
Measure	Percentage of eligible patients who enrol in the study	Percentage of participants with completed 90-day HbA1c	Percentage of participants experiencing ≥1 severe hypoglycaemic events (≤2.2mmol/l) during the intervention	Mean percentage time spent in target glycaemic range (4.0-6.9mmol/L) during the intervention period
Red	<66%	<80%	>20%	<60%
Amber	66 - 87%	80 - 100%	11 – 20%	60 - 70%
Green	>87%	100%	<11%	>70%

Feasibility Trial

HbA1c at 1 year



Full Trial

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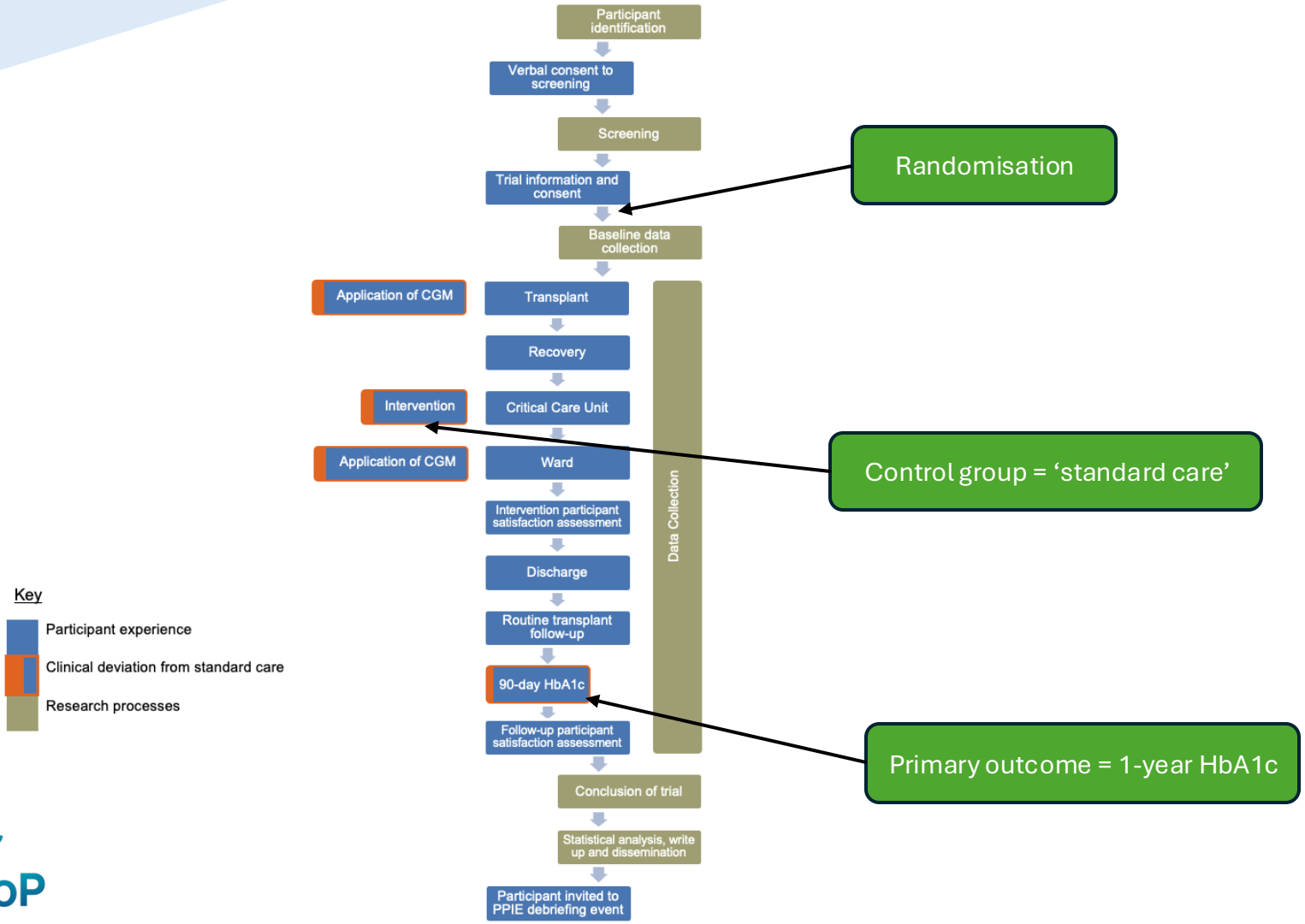
Participant identification
Verbal consent to screening
Screening
Trial information and consent
Baseline data collection
Application of CGM
Transplant
Recovery
Intervention
Critical Care Unit
Application of CGM
Ward
Intervention participant satisfaction assessment
Discharge
Routine transplant follow-up
90-day HbA1c
Follow-up participant satisfaction assessment
Conclusion of trial
Statistical analysis, write up and dissemination
Participant invited to PPIE debriefing event
Data Collection
Key
Participant experience
Clinical deviation from standard care
Research processes
Randomisation
Control group = 'standard care'
Primary outcome = 1-year HbA1c

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The team:

Mr D. van Dellen (Consultant Transplant Surgeon)

Mr R. Brown (SpR - Transplant Surgery)

Dr H. Thabit (Consultant Endocrinologist)

Dr J. Bannard-Smith (Consultant Intensivist)

Mr I. Shapey (Consultant Pancreatic Surgeon)

Dr Catherine Fullwood (Senior Statistician)

Mr Andrew Freeman (Patient Partner)

Mrs Tauseefha Bint-Taufiq (Patient Partner)

Sponsor:

Manchester University NHS Foundation Trust

Sponsored as non-CTIMP study

What's Next?

Funding 

Ethical approval 

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Please help by informing us what is your perioperative practice in following pancreas transplantation with this short survey:

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