# The relationship between treatment, implementation, and clinical effectiveness for two psychoeducational programmes for severe hypoglycaemia in type 1 diabetes: a quantitative analysis of the effectiveness-implementation hybrid type II trial

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## 1. Background

HARPdoc RCT

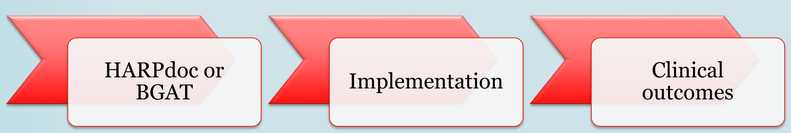
- Hybrid type II trial (3)
- Testing effectiveness-implementation of two programmes HARPdoc and BGAT, both targeting hypoglycaemia in people with type 1 diabetes at high risk for hypoglycaemia, and their implementation-related facilitators and barriers[1]

## 2. Aim

To understand if

→ implementation differs between treatment groups

→ implementation is associated with clinical outcomes




## 3. Data

**Implementation** – collected after treatment

- acceptability (AIM), appropriateness (IAM), feasibility (FIM) subscales[4]
- Total implementation score calculated by averaging subscales
- Surveys collected from participants, healthcare providers (HCP) and relatives

**Clinical** – collected at baseline and 12 months post-randomization

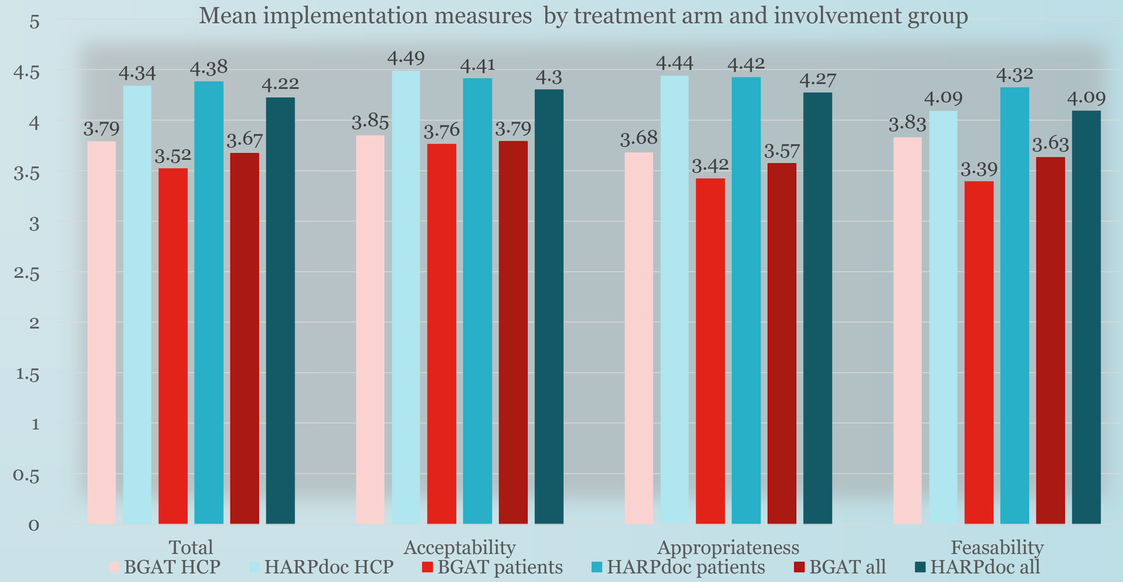
- Primary outcome: severe hypoglycaemia rates recalled over 12 months
- Secondary outcomes: attitudes to awareness (A2A), Hyperglycaemia Avoidance Survey (HAS), the Problem Areas in Diabetes (PAID), Hospital Anxiety and Depression Scores

## 4. Statistical analysis

- Linear regression to assess mean difference in implementation scores between treatment groups
- Generalised linear models to explore association between implementation scores and primary and secondary outcomes, adjusted for baseline

## 5. Treatment and implementation results

- N patients = 45, N HCP responses = 38, N relatives = 6
- Strong evidence that those involved in the HARPdoc treatment group found their course to be more acceptable, appropriate, feasible and overall implementable than those involved in the BGAT treatment
  - Difference of 0.55, 95% CI (0.22, 0.89), p = 0.0015
- The difference between the two courses was generally greater amongst the patients than the HCPs




| Implementation outcome | group | Difference (95% CI) | p-value |
|---|---|---|---|
| Aggregated implementation scores | All stakeholders | 0.55 (0.22, 0.89) | 0.0015 |
| | HCP | 0.55 (0.14, 0.96) | 0.0104 |
| | Patients | 0.86 (0.37, 1.34) | 0.0010 |
| AIM (acceptability) | All stakeholders | 0.50 (0.16, 0.85) | 0.0048 |
| | HCP | 0.64 (0.18, 1.10) | 0.0082 |
| | Patients | 0.65 (0.15, 1.14) | 0.0120 |
| IAM (adaptability) | All stakeholders | 0.69 (0.32, 1.06) | 0.0004 |
| | HCP | 0.76 (0.28, 1.24) | 0.0028 |
| | Patients | 1.00 (0.48, 1.53) | 0.0004 |
| FIM (feasibility) | All stakeholders | 0.46 (0.11, 0.81) | 0.0099 |
| | HCP | 0.25 (-0.14, 0.65) | 0.2018 |
| | Patients | 0.92 (0.38, 1.46) | 0.0013 |

## 6. Implementation and clinical outcomes results

- N patients = 45
- no evidence of a relationship between implementation and SH event rate
- But there is evidence that implementation scores are related to Problem Areas in Diabetes scores (difference of -4.49, 95%CI (-8.82, -0.16)) and anxiety (difference of -1.09, 95%CI (-2.16, -0.03))

## 7. Conclusions

- This is a novel hybrid type II trial which tested quantitatively implementation scores with clinical treatments and outcomes.
- Limitations include small sample size
- Importance of collecting implementation data from the start

## 8. References

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