How Standard is Standard Care?

Exploring Control Group Outcomes in Behaviour Change Interventions for Young People with Type 1 Diabetes

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Background

• RCT’s involve the comparison of outcomes between 2 or more groups (e.g. Intervention vs Control)

• For health care interventions, standard care is frequently used as control

• Standard Care is an active comparison and therefore it’s relative efficacy is integral to the outcomes of an RCT
Comparing an Intervention against Standard Care
Comparing an Intervention against Standard Care

ES = Positive

Intervention | Low Quality Standard Care | Moderate Quality Standard Care | High Quality Standard Care
Comparing an Intervention against Standard Care

ES = 0

- Intervention
- Low Quality Standard Care
- Moderate Quality Standard Care
- High Quality Standard Care
Comparing an Intervention against Standard Care

ES = Negative

- Intervention
- Low Quality Standard Care
- Moderate Quality Standard Care
- High Quality Standard Care
Standard Care Quality Determines Treatment Outcomes in Control Groups of HAART-Adherence Intervention Studies: Implications for the Interpretation and Comparison of Intervention Effects

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Maastricht University

Standard Care Impact on Effects of Highly Active Antiretroviral Therapy Adherence Interventions

A Meta-analysis of Randomized Controlled Trials

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Background: Poor adherence to medication limits the effectiveness of treatment for human immunodeficiency virus. Systematic reviews can identify practical and effective interventions. Meta-analyses that control for variability in standard care provided to control groups may produce more accurate estimates of intervention effects.

Methods: To examine whether viral load and adherence success rates could be accurately explained by the active content of highly active antiretroviral therapy (HAART) adherence interventions when controlling for variability in care delivered to controls, databases were searched for randomized controlled trials of HAART adherence interventions published from 1996 to January 2009. A total of 1342 records were retrieved, and 52 articles were examined in detail. Directly observed therapy and interventions targeting specific patient groups (i.e., psychiatric or addicted patients, patients <18 years) were excluded, yielding a final sample of 31 trials. Two cod-

Results: Twenty studies were included in the analyses. The content of adherence care provided to control and intervention groups predicted viral load and adherence success rates in both conditions ($P < .001$ for all comparisons), with an estimated impact of optimal adherence care of 55 percentage points. After controlling for variability in care provided to controls, the capacity of the interventions accurately predicted viral load and adherence effect sizes ($R^2 = 0.78$, $P = .02$; $R^2 = 0.28$, $P < .01$). Although interventions were generally beneficial, their effectiveness reduced noticeably with increasing levels of standard care.

Conclusions: Intervention and control patients were exposed to effective adherence care. Future meta-analyses of (behavior change) interventions should control for variability in care delivered to active controls. Clinical practice may be best served by implementing current best practice.
Standard Care Quality (SCQ) Varied Between HAART Trials

SCQ Predicted Control Group Outcomes

Controlling for SCQ Changes Findings in a Meta-analysis

(de Bruin et al., 2009; 2010)
Obtaining Articles

Systematic Searches of Electronic Databases
(MEDLINE, WoK, PsycInfo, CINHAL, Embase, Proquest)

Aged 8-21    Diagnosed > 6 Months
Glycated haemoglobin or a validated psychological measure
No samples with co-morbid illness
Standard care control condition

32,102 articles
552 abstracts screened after applying filters
48 full texts extracted
20 RCTs over 26 Published Articles
Methods

1. Assessed Standard Care Provision by:
   a) Extracting all details regarding standard care in published articles and supplementary online materials
   b) Primary authors were contacted to complete a checklist of activities delivered as part of standard care

2. Investigated the influence of standard care quality on medical and psychological outcomes via sub-group meta-analyses and meta-regression.
## Standard Care Quality Checklist

- 19 Standard care activities, including 15 BCTs

### Checklist

<table>
<thead>
<tr>
<th>Activity</th>
<th>Never</th>
<th>For some patients</th>
<th>For most patients</th>
<th>For all patients</th>
<th>Don’t know</th>
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</thead>
<tbody>
<tr>
<td>General information (verbal or written) about diabetes management</td>
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<td>Information about the consequences of sub-optimal control</td>
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<td>Encouragement of regular monitoring of blood glucose levels</td>
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<td>Feedback on most recent HbA1c /A1c</td>
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<td>Help plan for holidays, special events and sick days</td>
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<td>Discuss common barriers and ways to overcome them</td>
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<td>Identify individual problems relating to diabetes management and generate solutions</td>
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<td>Set personal goals for diabetes management (behaviour)</td>
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<td>Set personal targets for optimal HbA1c or Equivalent (outcome)</td>
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<td>Adherence to a dietary plan (e.g., carb counting)</td>
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<td>Use of alarms, cues or reminders to complete diabetes tasks</td>
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<td>More frequent contact for those with poor control or most difficulties</td>
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<td>Access to 24 hour telephone or online support for acute problems</td>
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<td>Contact with a psychologist</td>
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<tr>
<td>Contact with a Dietitian</td>
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<td>Liaison with relevant others (e.g., schools, employers) about diabetes</td>
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<td>Involve family members in diabetes self-care</td>
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<td>Provide contact details for relevant support groups</td>
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<td>Provide annual review</td>
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</table>

Never, Don’t Know = 0
Some Patients = 1
Most Patients = 2
All Patients = 3

Range: 0-57; $\alpha = .78$
Standard Care Reporting Was Limited

“…the control group attended the clinic for routine care during the study period”

(Viklund et al., 2007)

“Subjects were seen only at their routine visits”

(Charron-Prochownik et al., 2008)
Standard Care is Not Standard

The graph shows the frequency of scheduled patient contact for different intervals:

- **< 3 Months**: A small number of trials.
- **3 Months**: A significantly higher number of trials.
- **> 3 Months**: A moderate number of trials.
- **Did Not Report**: A moderate number of trials.

The data indicates that the frequency of scheduled patient contact differs from what is considered standard care.
Findings: Author Responses

- $N=17$, 85% Response Rate
- Number of activities delivered to all patients ranged from 2-15 ($M=9.94; SD=3.96$)
- Computed Standard Care Quality scores ranged from 27-52 ($M=40.82; SD=7.50$)
Influence of SCQ on Control Group Outcomes

- Control groups receiving higher SCQ scores (>42) had a larger pooled effect sizes for:

  Glycaemic control (.13 vs .02)

  Psychological Outcomes (.12 vs -.04)

- Meta-regression analysis showed a trend towards SCQ predicting psychological outcomes \((p = .158)\) but did not significantly predict glycaemic control outcomes.
Conclusions

Standard care is *NOT* standard

Standard care is inadequately reported

Standard Care has the potential to influence RCT outcomes
Recommendations

• Extend descriptions beyond service level features to active components of standard care

• Where space is limited, provide descriptions of standard care as online supplementary materials
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