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Improving outcomes for young people with type 1 diabetes.

Thesis Portfolio

THE UNIVERSITY
of EDINBURGH

Lorraine Lockhart
Doctorate in Clinical Psychology
The University of Edinburgh
May 2016
Acknowledgements

First and foremost, I would like to thank all the young people and parents who took the time to participate, without whom this study would not have been possible. I appreciated the interest that many families took in the study and their desire to improve outcomes for all young people with diabetes.

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Finally, I would to thank my family, in particular my husband, Gavin, and my parents, for their unwavering faith, love and support over the last three years. All my achievements have been made possible by them.
DClinPsychol Declaration of Own Work

Name: Lorraine Lockhart
Title of Work: Improving outcomes for young people with type 1 diabetes.

I confirm that this work is my own except where indicated, and that I have:

- Read and understood the Plagiarism Rules and Regulations
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- Clearly referenced/listed all sources as appropriate
- Referenced and put in inverted commas any quoted text of more than three words (from books, web, etc.)
- Given the sources of all pictures, data etc. that are not my own
- Not made undue use of essay(s) of any other student(s), either past or present (or where used, this has been referenced appropriately)
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Date 13/05/2016

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# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledgements</td>
<td>i</td>
</tr>
<tr>
<td>Declaration of Own Work</td>
<td>ii</td>
</tr>
<tr>
<td>Table of Contents</td>
<td>iii</td>
</tr>
<tr>
<td>List of Tables and Figures</td>
<td>iv</td>
</tr>
<tr>
<td>List of Appendices</td>
<td>v</td>
</tr>
<tr>
<td>Thesis Portfolio Overview</td>
<td>1</td>
</tr>
<tr>
<td>Thesis Portfolio Abstract</td>
<td>2</td>
</tr>
<tr>
<td>Chapter 1: Systematic Review</td>
<td>4</td>
</tr>
<tr>
<td>Abstract</td>
<td>5</td>
</tr>
<tr>
<td>Introduction</td>
<td>6</td>
</tr>
<tr>
<td>Aims</td>
<td>9</td>
</tr>
<tr>
<td>Methods</td>
<td>9</td>
</tr>
<tr>
<td>Results</td>
<td>12</td>
</tr>
<tr>
<td>Discussion</td>
<td>27</td>
</tr>
<tr>
<td>Conclusion</td>
<td>32</td>
</tr>
<tr>
<td>References</td>
<td>32</td>
</tr>
<tr>
<td>Chapter 2: Empirical Article</td>
<td>39</td>
</tr>
<tr>
<td>Abstract</td>
<td>40</td>
</tr>
<tr>
<td>Introduction</td>
<td>42</td>
</tr>
<tr>
<td>Aims</td>
<td>46</td>
</tr>
<tr>
<td>Methods</td>
<td>47</td>
</tr>
<tr>
<td>Results</td>
<td>54</td>
</tr>
<tr>
<td>Discussion</td>
<td>60</td>
</tr>
<tr>
<td>Conclusion</td>
<td>65</td>
</tr>
<tr>
<td>References</td>
<td>66</td>
</tr>
<tr>
<td>Thesis Portfolio References</td>
<td>73</td>
</tr>
<tr>
<td>Thesis Word Count (Excluding references and appendices)</td>
<td>19,616</td>
</tr>
</tbody>
</table>
# List of Tables and Figures

## Chapter 1 Systematic Review

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1</td>
<td>PRISMA flow diagram</td>
<td>13</td>
</tr>
<tr>
<td>Table 1</td>
<td>Characteristics of included studies</td>
<td>16</td>
</tr>
<tr>
<td>Table 2</td>
<td>Summary of methodological review and quality ratings</td>
<td>21</td>
</tr>
</tbody>
</table>

## Chapter 2 Empirical Article

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1</td>
<td>Demographic and clinical characteristics of adolescents and parents</td>
<td>54</td>
</tr>
<tr>
<td>Table 2</td>
<td>Means and significant correlations among demographic, clinical and primary outcomes</td>
<td>56</td>
</tr>
<tr>
<td>Table 3</td>
<td>Regression model parameters predicting treatment adherence</td>
<td>58</td>
</tr>
<tr>
<td>Table 4</td>
<td>Regression model parameters predicting quality of life</td>
<td>59</td>
</tr>
</tbody>
</table>

## Appendices

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table D2</td>
<td>Excluded studies and reasons for exclusion</td>
<td>102</td>
</tr>
<tr>
<td>Figure I.1</td>
<td>Scatterplot of standardised residuals and standardised predicted values for treatment adherence analysis.</td>
<td>118</td>
</tr>
<tr>
<td>Figure I.2</td>
<td>Scatterplot of standardised residuals and standardised predicted values for QoL analysis.</td>
<td>118</td>
</tr>
<tr>
<td>Figure I.3</td>
<td>Histogram of standardised residuals for treatment adherence model.</td>
<td>111</td>
</tr>
<tr>
<td>Figure I.4</td>
<td>Histogram of standardised residuals for QoL model.</td>
<td>111</td>
</tr>
<tr>
<td>Figure I.5</td>
<td>Normal P-plot of standardised residuals in treatment adherence model</td>
<td>119</td>
</tr>
<tr>
<td>Figure I.6</td>
<td>Normal P-plot of standardised residuals in QoL model.</td>
<td>119</td>
</tr>
</tbody>
</table>
### List of Appendices

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix A</td>
<td>Journal of Pediatric Psychology Instructions for Authors</td>
<td>89</td>
</tr>
<tr>
<td>Appendix B</td>
<td>Journal of Contextual Behavioural Science Instructions for Authors</td>
<td>93</td>
</tr>
<tr>
<td>Appendix C</td>
<td>Quality Criteria Tool</td>
<td>98</td>
</tr>
<tr>
<td>Appendix D</td>
<td>Excluded Studies</td>
<td>102</td>
</tr>
<tr>
<td>Appendix E</td>
<td>Information Sheets</td>
<td>104</td>
</tr>
<tr>
<td>Appendix F</td>
<td>Consent Forms</td>
<td>110</td>
</tr>
<tr>
<td>Appendix G</td>
<td>Ethical Opinion</td>
<td>112</td>
</tr>
<tr>
<td>Appendix H</td>
<td>Tests of Assumptions for Regression Analysis</td>
<td>116</td>
</tr>
<tr>
<td>Appendix I</td>
<td>Thesis Lay Summary</td>
<td>121</td>
</tr>
</tbody>
</table>
Thesis Portfolio Overview

The thesis is presented in a portfolio format. The portfolio will be submitted in part-fulfilment of the Doctorate in Clinical Psychology at the University of Edinburgh.

An abstract summarising the aims, methods, results and conclusions of the thesis is presented prior to the main chapters.

Chapter 1 presents a systematic review of studies evaluating the effectiveness of interventions in improving health-related quality of life for children and adolescents with type 1 diabetes. The review is presented in journal article format and was prepared in accordance with the instructions for authors from Journal of Paediatric Psychology using APA style. These guidelines can be viewed in Appendix A.

Chapter 2 presents an empirical study which aimed to explore the relationships between psychological flexibility, mindfulness, parenting and health outcomes in adolescents with type 1 diabetes. The study is presented in journal article format and has been prepared in accordance with the instruction for authors from Journal of Contextual Behavioral Science. These guidelines can be viewed in Appendix B.

A full thesis reference list is provided prior to the appendices and are presented in APA style, consistent with chapters in the portfolio.
Thesis Abstract

Aims: The thesis aimed to contribute to the current understanding of how to improve comprehensive health outcomes for children and adolescents with type 1 diabetes.

Methods: A systematic review was undertaken to identify existing interventions designed to improve health-related quality of life in a paediatric diabetes population. The quality of identified studies was assessed and the effectiveness of the interventions was evaluated. Parent-adolescent dyads were also recruited via paediatric diabetes teams to participate in an empirical study. Participants were asked to complete questionnaires measuring psychological flexibility, mindfulness, perception of parental care and control, adherence to treatment and quality of life. Relationships were explored using correlation and regression analysis.

Results: Twenty seven articles were identified in the systematic review. More than half were rated as “acceptable” or “high quality”. Quality of life was a primary treatment target in only three studies. Eight studies reported significant beneficial effects on health-related quality of life. In the empirical study, regression analysis found that both parent and adolescent diabetes-specific psychological flexibility predicted treatment adherence while adolescent mindfulness and insulin administration predicted quality of life.

Conclusion: There is some evidence for the effectiveness of intensive structured education and coping skills training in improving health-related quality. However consideration should be given to developing theoretically informed interventions to target quality of life alongside other treatment related outcomes. The
empirical study suggested psychological flexibility and mindfulness are useful constructs for understanding health outcomes in adolescents with type 1 diabetes. Acceptance and commitment, and mindfulness-based therapies may prove beneficial for improving outcomes in this population.
Chapter 1

Psychologically informed interventions to improve health related quality of life in children and adolescents with type 1 diabetes: A systematic review.

Lorraine Lockhart
University of Edinburgh and NHS Forth Valley

Word Count (excluding references and tables): 6198
Abstract

Objective: To systematically review the literature to identify interventions aiming to improve health-related quality of life in children and adolescents with type 1 diabetes and to evaluate their effectiveness.

Methods: A search was undertaken to identify studies, published prior to 2016, evaluating interventions for children and adolescents with type 1 diabetes which reported quality of life outcomes. An assessment of the risk of bias was undertaken to evaluate the quality of published evidence.

Results: Twenty seven articles were identified. More than half were rated as “acceptable” or “high quality”. Significant beneficial effects on health-related quality of life outcomes were reported in 8 studies.

Conclusions: Few interventions were designed to target quality of life outcomes. There is some evidence for the effectiveness of intensive structured education and coping skills training. Consideration should be given to developing theoretically informed interventions to target quality of life outcomes alongside other treatment related outcomes.

Keywords

Quality of life, treatment, type 1 diabetes, children, adolescent.
1. Introduction

1.1 Type 1 Diabetes

Type 1 Diabetes (T1D) is a chronic condition that affects around 188 per 100,000 young people in the UK (Royal College of Paediatrics and Child Health, 2015). Young people with T1D are at increased risk of serious complications, including hypoglycaemia and hyperglycaemia in the short term and retinopathy and neuropathy in the longer term (Currie et al., 2013; Diabetes Control and Complications Trial Research Group [DCCT], 1993; Nathan, 1993). Results from a large scale study in the US concluded that long-term complications could be mitigated by maintaining close to normal blood glucose levels through an intensive treatment regime of blood glucose monitoring, carbohydrate counting, insulin administration and exercise (DCCT, 1993).

The daily management of diabetes falls with the family, and parental involvement in treatment throughout childhood and adolescence has consistently been shown to improve adherence and blood glucose levels (Anderson, Ho, Brackett, Finkelstein, & Laffel, 1997; Wysocki et al., 1996). However the intensive and pervasive nature of the treatment can lead to increased stress and burden with burnout and depressive symptoms common in both young people and parents (Davidson, Penney, Muller, & Grey, 2004; Lindström, Åman, & Norberg, 2011). For some young people, particularly during adolescence, adherence to treatment and glycaemic control remains challenging (Levine et al., 2001; Mortensen & Hougaard, 1997).

Interventions designed to equip families with the knowledge and skills necessary to cope with the demands of diabetes have become a cornerstone of
diabetes treatment (National Institute for Health and Care Excellence [NICE], 2015). Treatment approaches have been wide-ranging, including psychoeducational (Murphy et al., 2012; Price et al., 2016), behavioural (Jaser, Patel, Rothman, Choi, & Whittemore, 2014; Maranda, Lau, Stewart, & Gupta, 2015) and family therapy (Kichler, Kaugars, Marik, Nabors, & Alemzadeh, 2013; Mayer-Davis et al., 2015). Previous systematic reviews and meta-analyses have concluded such interventions have a small to medium effect in improving clinical outcomes in adolescents, such as glycaemic control (Couch et al., 2008; Hampson et al., 2001; Pillay et al., 2015).

1.2 Health-Related Quality of Life

It is clear from these reviews that physical health and adherence to treatment have been the focus of intervention evaluations. However the World Health Organisation defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (Grad, 2002). This conceptualisation of health has perhaps become more relevant in recent decades as medical and technological advances mean conditions, including diabetes, which were once life-limiting are now considered manageable but can come at the cost of significant and life-long healthcare needs (DCCT, 1993). There is increasing recognition of the need to consider how a person can live a full life in the context of their chronic condition (Eiser & Morse, 2001; Polonsky, 2002).

Health-related quality of life (HRQOL) is a multi-dimensional construct that refers to a person’s subjective perception of the impact of health and healthcare on their physical, psychological (cognitive and emotional) and social well-being (Matza, Swensen, Flood, Secnik, & Leidy, 2004). HRQOL has become an important patient reported outcome in clinical trials and for some it is the primary outcome
There has also been a concurrent rise in the number of standardised and validated measures of both generic and disease-specific HRQOL (Ingersoll & Marrero, 1991; Varni, Burwinkle, Seid & Skarr, 2003).

1.3 Health-Related Quality of Life and Paediatric Diabetes

Children and adolescents with T1D have been shown to have poorer HRQOL than healthy populations (Varni, Burwinkle, Jacobs et al., 2003), suggesting this is an important treatment target for this population. The multi-dimensional nature of HRQOL is emphasised in findings that metabolic control and HRQOL often do not improve simultaneously (Ingerski, Laffel, Drotar, Repaske, & Hood, 2010). Studies exploring the relationship between diabetes-related factors, including number of injections, insulin dosage and frequency of blood glucose monitoring, with HRQOL have been inconsistent (Ingerski et al., 2010; Laffel, Connell, et al., 2003). This suggests the extent to which a young person “feels better” is only partly related to improvement in physical symptoms. This is supported by studies showing HRQOL in children and adolescents with diabetes is related to a number of psychological factors, including depression, negative affect and coping style (Grey, Boland, Yu, Sullivan-Bolyai, & Tamborlane, 1998; Ingerski et al., 2010; Lawrence et al., 2012). Family factors, such as family conflict, responsive parenting and parental control are also related to HRQOL outcomes (Botello-Harbaum, Nansel, Haynie, Iannotti, & Simons-morton, 2008; Graue, Wentzel-Larsen, Hanestad, & Sovik, 2005b). This lends support to the notion that focussing the evaluation of interventions on improvement in diabetes-management outcomes may not provide a sufficient assessment of the overall well-being of young people with diabetes.
To date, HRQOL outcomes have been poorly covered in systematic reviews. Pillay et al. (2015) concluded there was insufficient evidence to support the effectiveness of behavioural interventions in improving HRQOL due to the small number of studies employing this outcome measure. Similarly, a systematic review of psychoeducational interventions found only 4 out of the 8 identified studies included measures of HRQOL (Couch et al., 2008). Another by Lohan et al. (2015) reviewing the effectiveness of parenting interventions for parents of children with type 1 diabetes failed to find any study meeting their criteria who reported HRQOL outcomes. Each of these reviews included restricted criteria for the type of intervention included.

2. Aims of Current Review

Despite the recognition of the importance of HRQOL as a treatment target in paediatric diabetes there has been no attempt to date to systematically review the effectiveness of a range of interventions in improving this outcome. The aims of the current review are therefore:

- to identify any interventions with specific aims to improve HRQOL in children and adolescents with type 1 diabetes, and
- to evaluate the effectiveness of interventions in improving HRQOL in children and adolescents with type 1 diabetes

3. Method

3.1 Eligibility Criteria for Inclusion in Review

3.1.1 Type of study. To ensure a wide coverage of potentially effective interventions the review was not limited to randomised controlled trials. Studies
were therefore eligible for inclusion provided pre- and post-treatment outcomes were reported for at least 1 group participating in an intervention.

3.1.2 Participants. All participants must have a diagnosis of type 1 diabetes and be aged between 0-18 years. Studies with participants outside this age range were excluded, as were those that combined patients with diabetes and other chronic illnesses.

3.1.3 Intervention. Studies were considered for inclusion if they described interventions that included a psychologically informed approach provided in addition to medical care. There was no requirement for interventions to be specifically designed to improve quality of life (QoL) and could include components designed to improve adherence to medical treatments, skills required for treatment, adjustment and family functioning. Education interventions were considered eligible for the review if they included components beyond the provision of knowledge (e.g. managing diabetes in everyday life, problem solving treatment issues).

3.1.4 Outcomes. To date there is no agreed specific definition of Quality of Life however it is generally agreed that it is a multi-dimensional construct that includes the impact of health or a health conditions beyond the physical domain (Matza et al., 2004). For the purposes of the current review QoL was defined as the perceived impact of a health condition on the physical, social and psychological well-being of the young person. This could include health as a generic construct or specifically related to diabetes. Robust outcome measures of QoL in children and young people have been extensively validated (e.g. Diabetes Quality of Life-Youth [DQOL-Y]; Ingersoll & Marrero, 1991; and Pediatric Quality of Life [Peds-QL]; Varni, Burwinkle, Seid, et al., 2003). Given such measures are widely available only
studies utilising a standard and psychometrically-sound measure, which were based on multidimensional definition of QoL were included in the review.

3.2 Search Strategy

Electronic searches were undertaken on the Medline, PsychInfo, Embase and CINAHL databases. No date restrictions were placed on the search and included all studies available until February 2016. Searches were restricted to peer-reviewed journals only. Searches were conducted using the keyword function in all databases and included the following search terms: “diabetes” AND “type 1” AND “quality of life” AND “adolescen*” OR “child*” OR “teen*” OR “you*” AND “intervention” OR “treatment”. Reference lists of identified studies were also reviewed for potentially relevant studies.

3.3 Review Process

3.3.1 Study selection. Following the database search all citations and abstracts were exported to reference management software (Endnote) and duplicates were removed. Titles and abstracts were screened and studies not meeting the inclusion criteria were excluded. Full texts for all remaining studies were reviewed to determine eligibility for inclusion.

3.3.2 Data collection. A data collection tool designed for the purposes of this review was used to extract relevant data. Data extracted from studies included author details, publication source, country of origin, participant details (e.g. mean age and sex), study design, description of interventions, outcome measures, results and key conclusions.

3.3.3 Assessment of risk of bias and quality of evidence. A specific tool was developed to extract details of study design, conduct and reporting known to
impact on the risk of bias inherent in studies. The development of the tool was based on templates provided by the Cochrane Handbook for Systematic Reviews (Higgins & Green, 2011) and SIGN 50 guideline (Scottish Intercollegiate Guidelines Network [SIGN], 2015). A copy of the tool is provided in Appendix C. Studies were assessed on each criteria in the tool, which were noted to be present or absent. This assessment of risk of bias was then used to evaluate the overall quality of the evidence presented in each study. There was no plan to exclude studies based on quality assessment. Therefore an adapted version of the SIGN 50 designations was adopted so studies could be assessed as “high quality”, “adequate” or “low quality”.

4. Results

4.1 Search Results

The database searches identified 1057 articles, including 174 duplicates. Abstracts of the remaining 883 were screened for eligibility and 68 were identified as potentially suitable. The full-texts of the remaining 68 articles were reviewed and 26 were retained for inclusion (see Appendix D for details of excluded studies). The reference lists of the retained studies were also reviewed for potentially suitable articles. Only 1 further article was identified, resulting in 27 articles, representing 22 individual studies, being included (Figure 1). For the remainder of the review, articles reporting data from the same study will be considered as one study and only the last associated published article will be cited. The review will therefore include 22 studies.

4.2 Study Characteristics

4.2.1 Study design. An overview of the study characteristics is provided in Table 1. The majority of studies were RCTs, (n= 19), four of which were cluster
randomised. Non-active control arms (e.g. treatment as usual) were present in 11 RCTs, with others being compared to an active intervention (e.g. structured education). The remaining three studies were uncontrolled evaluations. Table 1. Characteristics of included studies.

Figure 1. Prisma flow diagram
4.2.2 Nationality. Around half of the included studies (n = 12) were undertaken in the USA. Others were carried out in the UK (n = 7), Norway (n = 2) and Germany (n = 1).

4.2.3 Participants. Participants ranged in age from 4 – 18 years, with reported mean ages ranging from 9.9 years to 15.5 years. Reported mean duration of diabetes ranged from 2.7 years (Laffel, Vangsness, et al., 2003) to 9.2 years (Channon et al., 2007). All but five studies (Graue et al., 2005a; Loding et al., 2008; Murphy et al., 2012; Newton & Ashley, 2013; Waller et al., 2008) specified significant co-morbid physical and/or psychiatric conditions as exclusion criteria. In general, the cluster-RCT’s had larger sample sizes than other studies, ranging from 205 to 575 participants, with a mean of 372.75 (SD = 155.9). Other RCTs reported sample sizes of 28 to 320 with a mean of 96.6 (SD = 80.39). The uncontrolled studies had sample sizes between 19 and 107 with a mean of 58 (SD = 44.84).

4.2.4 Interventions. Group interventions were evaluated in nine studies. Young people and parents attended groups separately in six interventions (Graue et al., 2005a; Grey et al., 2009; Loding et al., 2008; Price et al., 2016; Von Sengbusch et al., 2006; Waller et al., 2008) and attended together in three interventions (Christie et al., 2014; Murphy et al., 2012; Murphy et al., 2007). The majority of the group interventions were structured diabetes education (n = 8) with additional psychological and psychosocial components. Additional components included parental responsibility and communication (Murphy et al., 2012; Murphy et al., 2007), coping with diabetes in everyday life (Graue et al., 2005a; Price et al., 2016; Von Sengbusch et al., 2006; Waller et al., 2008), motivational interviewing (MI; Christie et al., 2014), problem solving and emphasising peer support and shared experience (Graue et al., 2005a; Loding et al., 2008).
The Graue (2005a) study also included three computer-assisted individual
counselling sessions in addition to group sessions. The final group intervention was
coping skills training (CST) for school-aged children (Grey et al., 2009).

Individual interventions were evaluated in six of the included studies, all of
which were RCTs. The majority of individual interventions (n = 4) were based on
MI techniques. In the Channon (2007) study young people received MI sessions with
a trained clinician in the community. The Robling (2012) study incorporated MI
within routine clinic-based appointments. The Wang (2010) study compared MI-
based education sessions with traditional structured education. The Nansel (2007)
study evaluated a multi-component treatment guided by MI principles but also
utilised applied behaviour analysis and problem solving. In the final two studies
participants were given instructions to follow at home. Maranda and colleagues
(2015) described a behavioural intervention where young people were instructed to
also described a behavioural intervention based on positive psychology where young
people received a preferred gift every 2 weeks and were encouraged to use gratitude
and self-affirmations when testing blood glucose.

Family focussed interventions were evaluated in five studies, all of which
were RCTs. Three of the family-focussed interventions delivered psychoeducation
to parent-child dyads within quarterly clinic appointments (Holmes et al., 2014; Katz
et al., 2014; Laffel, Vangsness, et al., 2003). Psychoeducation focussed on the need
for shared responsibility for diabetes treatment, effective family communication,
realistic expectations and shared goal setting. The Holmes (2014) study also included
coping skills training.
<table>
<thead>
<tr>
<th>Study (Country)</th>
<th>Country</th>
<th>Age Range (Mean)</th>
<th>Sample Size</th>
<th>Design</th>
<th>Intervention Type</th>
<th>Control Arm</th>
<th>Outcome Measure</th>
<th>Key Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Ambrosino et al., 2008)</td>
<td>USA</td>
<td>8 – 12 (9.9)</td>
<td>82</td>
<td>RCT</td>
<td>Coping skills training</td>
<td>Structured education</td>
<td>DQoL-Y - subscales</td>
<td>At 3 months significant improvement on all subscales for both groups but no group differences. At 12 months significant improvement on worry subscale for both groups but no group differences.</td>
</tr>
<tr>
<td>(Grey et al., 2009)</td>
<td>UK</td>
<td>14 – 17 (15.4)</td>
<td>66</td>
<td>RCT</td>
<td>Motivational interviewing (MI)</td>
<td>Supportive visits</td>
<td>DQoL-Y - subscales</td>
<td>At 12 months significant improvements for MI group on all subscales. At 24 months improvements maintained for impact and satisfaction subscales.</td>
</tr>
<tr>
<td>(Channon et al., 2007)</td>
<td>USA</td>
<td>10 – 17 (14.2)</td>
<td>28</td>
<td>RCT</td>
<td>Pet care behavioural intervention</td>
<td>Treatment as usual</td>
<td>Ped-QL – generic and diabetes specific - subscales</td>
<td>No significant effect on any QoL subscales.</td>
</tr>
<tr>
<td>(Maranda et al., 2015)</td>
<td>USA</td>
<td>11 – 14 (12.3)</td>
<td>320</td>
<td>RCT</td>
<td>Online coping skills training</td>
<td>Online diabetes education</td>
<td>PedsQL – generic – total scores</td>
<td>At 6 months and 12 months significant improvements in QoL for both groups but no group differences. Participants who received both interventions improved significantly on QoL compared with those who completed one intervention.</td>
</tr>
<tr>
<td>(Whittemore et al., 2012)</td>
<td>USA</td>
<td>11 – 17 (15.2)</td>
<td>30</td>
<td>RCT</td>
<td>Positive affect intervention</td>
<td>Education materials posted – attention control</td>
<td>Ped-QL – diabetes - total scores</td>
<td>No significant effect on QoL compared to education control.</td>
</tr>
<tr>
<td>(Jaser, Patel et al., 2014)</td>
<td>USA</td>
<td>13 – 17 (15.2)</td>
<td>39</td>
<td>RCT</td>
<td>Structure education and psychoeducation</td>
<td>Wait list control</td>
<td>Peds-QL – diabetes specific – total</td>
<td>No significant effect on QoL compared with wait list control.</td>
</tr>
<tr>
<td>(Murphy et al., 2007)</td>
<td>UK</td>
<td>6 – 16 (12.9)</td>
<td>67</td>
<td>RCT</td>
<td>Personal trainer (MI, ABA, problem solving)</td>
<td>Education (booklet only)</td>
<td>DQOL-Y - subscales</td>
<td>At 12 months control group displayed significantly better scores on QoL impact scale than intervention group.</td>
</tr>
<tr>
<td>(Nansel et al., 2007)</td>
<td>USA</td>
<td>11 – 16 (13.8)</td>
<td>81</td>
<td>RCT</td>
<td>Multi-component (education, behaviour)</td>
<td>Wait list control</td>
<td>Peds-QL – generic and diabetes – total scores</td>
<td>At 6 months control group displayed significantly greater QoL than intervention group at follow up.</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Age Range</td>
<td>Sample Size</td>
<td>Intervention</td>
<td>Comparator</td>
<td>Outcome Measure</td>
<td>Findings</td>
<td></td>
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<tr>
<td>(Loding, Wold, Skavhaug, &amp; Graue, 2007)</td>
<td>Norway</td>
<td>13 – 18 (14.9)</td>
<td>19</td>
<td>Pre-post treatment</td>
<td>Peer support and problem solving group</td>
<td>n/a</td>
<td>DQoL-Y – subscales</td>
<td>No significant changes in QoL at follow up.</td>
</tr>
<tr>
<td>(Loding et al., 2008)</td>
<td></td>
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</tr>
<tr>
<td>(Murphy et al., 2012)</td>
<td>UK</td>
<td>11 – 16 (13.1)</td>
<td>205</td>
<td>Cluster - RCT</td>
<td>Structured education and psychoeducation</td>
<td>Treatment as usual</td>
<td>DQoL-Y – sf – subscales</td>
<td>No significant changes in QoL at follow up.</td>
</tr>
<tr>
<td>(Katz et al., 2014)</td>
<td>USA</td>
<td>8 – 16 (13.0)</td>
<td>153</td>
<td>RCT</td>
<td>Family-based psychoeducation and teamwork + Care Ambassador</td>
<td>1. Care Ambassador + outreach phone calls  2. Care Ambassador only (TAU)</td>
<td>Peds-QL – generic – total scores</td>
<td>No significant effect on QoL compared with controls at follow up.</td>
</tr>
<tr>
<td>(Laffel, Vangsness, et al., 2003)</td>
<td>USA</td>
<td>8 – 17 (12.1)</td>
<td>100</td>
<td>RCT</td>
<td>Family-focused teamwork.</td>
<td>Treatment as usual</td>
<td>Peds-QL – generic – total scores</td>
<td>No significant effect on QoL compared with controls at follow up.</td>
</tr>
<tr>
<td>(Von Sengbusch et al., 2006)</td>
<td>Germany</td>
<td>8 – 16 (11.1)</td>
<td>107</td>
<td>Pre-post</td>
<td>Mobile structured education</td>
<td>n/a</td>
<td>KINDL – generic and diabetes specific – subscales</td>
<td>At 6 months significant improvements in self-esteem subscale and diabetes-related scale.</td>
</tr>
<tr>
<td>(Newton &amp; Ashley, 2013)</td>
<td>USA</td>
<td>13 – 18 (14.5)</td>
<td>59</td>
<td>RCT</td>
<td>Online psychosocial intervention (peer support, problem solving)</td>
<td>Treatment as usual</td>
<td>DQoL-Y – total score</td>
<td>No significant effect on QoL compared with controls at follow up.</td>
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<tr>
<td>(Holmes et al., 2014)</td>
<td>USA</td>
<td>11 – 14 (12.84)</td>
<td>226</td>
<td>RCT</td>
<td>Family teamwork and coping skills.</td>
<td>Supportive education intervention.</td>
<td>PedsQL – diabetes specific – total scores</td>
<td>At 18 months both groups showed improvements in QoL but no differences between groups.</td>
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<td>(Gregory et al., 2011)</td>
<td>UK</td>
<td>4 – 15 (10.6)</td>
<td>575</td>
<td>Cluster-RCT</td>
<td>Motivational interviewing consulting skills</td>
<td>Treatment as usual</td>
<td>PedsQL – diabetes specific – subscales</td>
<td>At 12 months significant improvements for control group on barriers to treatment and treatment adherence subscales but no improvements for intervention group.</td>
</tr>
<tr>
<td>(Robling et al., 2012)</td>
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<tr>
<td>(Waller et al., 2008)</td>
<td>UK</td>
<td>11 – 16 (13.6)</td>
<td>48</td>
<td>Pre-post</td>
<td>Structured education – KICk-OFF course.</td>
<td>n/a</td>
<td>PedsQL – generic and diabetes specific – total scores.</td>
<td>At 6 months significant improvements in generic and diabetes-related QoL.</td>
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<td>Study (Year)</td>
<td>Country</td>
<td>Age Range</td>
<td>Sample Size</td>
<td>Type</td>
<td>Intervention Details</td>
<td>Control Details</td>
<td>Outcomes</td>
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</tr>
<tr>
<td>Price et al., 2016</td>
<td>UK</td>
<td>11 – 16 (13.71)</td>
<td>396</td>
<td>Cluster-RCT</td>
<td>Structured education – KICK-OFF course.</td>
<td>Treatment as usual</td>
<td>PedsQL – generic and diabetes specific – subscales and total scores.</td>
<td>At 6 months significant improvement for intervention group on all generic QoL scores and diabetes specific symptoms subscale compared with control group. At 12 months significant improvements for intervention group on generic QoL total score compared with control group. At 24 months no significant improvement for intervention group on any scores compared with control group. At 12 and 24 months significant improvements for control group on treatment adherence subscale compared with intervention group.</td>
</tr>
<tr>
<td>Wang et al., 2010</td>
<td>USA</td>
<td>12 – 18 (15.5)</td>
<td>54</td>
<td>RCT</td>
<td>Motivational interviewing-based education</td>
<td>Structured education</td>
<td>EDIC-QOL – subscales</td>
<td>No significant effect on QoL for MI group compared with control group at follow up.</td>
</tr>
<tr>
<td>Christie et al., 2014</td>
<td>UK</td>
<td>8 – 16 (13.1)</td>
<td>315</td>
<td>Cluster-RCT</td>
<td>Structured education using psychological approaches (MI)</td>
<td>Treatment as usual</td>
<td>PedsQL – generic and diabetes specific – subscales and total scores.</td>
<td>No significant effect on QoL for intervention group compared with controls at follow up.</td>
</tr>
<tr>
<td>Mayer-Davis et al., 2015</td>
<td>USA</td>
<td>12 – 16 (13.9)</td>
<td>61</td>
<td>RCT</td>
<td>Multi-component (MI, problem-solving, behavioural family systems therapy)</td>
<td>Treatment as usual</td>
<td>PedsQL – generic – total scores. PDQ – diabetes specific – total scores.</td>
<td>No significant effect on diabetes QoL for intervention group compared with control group.</td>
</tr>
<tr>
<td>Graue et al., 2005a</td>
<td>Norway</td>
<td>11 – 17 (14.2)</td>
<td>101</td>
<td>RCT</td>
<td>Structured education and counselling</td>
<td>Treatment as usual</td>
<td>DQoL-Y – diabetes specific – subscales</td>
<td>At 15 months significant improvements for intervention group on diabetes specific impact subscale and generic family activities subscale compared with control group.</td>
</tr>
</tbody>
</table>

Note. Age = years, RCT = Randomised Controlled Trial, QoL = Quality of Life, DQOL-Y = Diabetes Quality of Life- Youth Scale, CST = Coping Skills Training, MI = Motivational Interviewing, Peds-QL= Pediatric Quality of Life Scale, ABA = Applied Behaviour Analysis, DQOLY-sf = Diabetes Quality of Life-short form, TAU = Treatment As Usual, EDIC-QOL = Epidemiology of Diabetes Interventions and Complication Quality of Life Scale, PDQ = Pediatric Quality, CHQ = Child Health Questionnaire.
The remaining two family-focussed interventions were multi-component. The Kichler (2013) study incorporated group education sessions with family sessions using a combination of education, behaviour therapy and play therapy. The Mayer-Davis (2015) study incorporated elements of MI, problem solving and behavioural family systems therapy approaches.

Online interventions were evaluated in two RCT studies. The Jaser, Whittemore (2014) study compared two online interventions; one providing CST and another providing general diabetes education. Participants were given the opportunity to cross-over to the alternate intervention during a follow up period. The Newton (2013) study evaluated a website utilising various functions including forums, live chat and blogs to increase peer support, facilitate problem solving and encourage goal setting in relation to a different weekly psychosocial issue.

4.3 Quality of Studies

4.3.1 Overall ratings. An overview of the quality review is provided in Table 2. Of the 22 studies included in the review, five were rated as “high quality”. Of the remaining 17 studies, eight were rated as “acceptable” and nine were rated as “low quality”.

4.3.2 Quality of study design. A major strength of this body of literature was the large proportion of randomised controlled trials (RCT), with only three studies being uncontrolled. However, in five of these the risk of selection bias was unknown as insufficient detail was provided to assess the rigour of the randomisation process. In addition, only four indicated that the blinding of group assignment had been considered at baseline and post-treatment assessment. Indeed, the nature of psychological interventions means it is difficult for blinding to take place,
particularly for participants, for the duration of the study. The majority of studies also reported at least 6 months follow up assessment. However, three of the four who did not were identified as pilot and/or feasibility studies (Maranda et al., 2015; Mayer-Davis et al., 2015; Newton & Ashley, 2013).

For the purposes of the review, sample size was considered adequate where a pre-determined recruitment target had been achieved based on an appropriate power calculation. If a power calculation was not provided a sample size of 51 per group was considered adequately powered (0.8) to detect a medium effect size (0.5) between groups, with significance p < 0.05. Based on these criteria, only nine studies had an adequate sample size. Some studies only provided a power calculation based on the necessary sample size to detect a meaningful change in HbA1C levels (Christie et al., 2014; Graue et al., 2005a; Gregory et al., 2011; Maranda et al., 2015; Murphy et al., 2007; Nansel et al., 2007). Only two studies considered power within the context of QoL outcomes (Jaser, Whittemore, et al., 2014; Price et al., 2016).

4.3.3 Quality of sample. The representativeness of the samples included in the study was mixed. There was a general tendency for studies to be comprised mostly of participants from white, middle to high earning families (e.g. Jaser, Patel, et al., 2014). There were however notable exceptions. For example, the Jaser, Whittemore, (2014) study was able to recruit higher proportions of non-white participants than other studies. Children diagnosed with type 1 diabetes should receive care via (at least) quarterly outpatient appointments with a multidisciplinary team (NICE, 2015; DCCT, 1993).
<table>
<thead>
<tr>
<th>Study</th>
<th>Control</th>
<th>Randomised</th>
<th>Concealed</th>
<th>Follow Up</th>
<th>Sample</th>
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<th>Confounds</th>
<th>Attrition</th>
<th>Intervention</th>
<th>Fidelity</th>
<th>Outcomes</th>
<th>Analysis</th>
<th>ITT</th>
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<tr>
<td>Jaser, Whittemore (2014)</td>
<td>✔</td>
<td>✔</td>
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</tr>
<tr>
<td>Jaser, Patel (2014)</td>
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<tr>
<td>Murphy (2007)</td>
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<td>Mayer-Davis (2015)</td>
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<td>8/13 Acceptable</td>
</tr>
</tbody>
</table>

Note. See Appendix A for description of each criteria
This means clinic populations are likely to be generally similar to the actual populations of children with type 1 diabetes in any given area. All but one study (Kichler et al., 2013) used such clinic populations as a convenience sample and approached eligible participants to invite them on to the study. The reporting of the number of eligible participants varied. In those who did report these figures there were discrepancies across studies with some able to recruit a high percentage of those eligible, for example (Katz et al., 2014), while others had low uptake (e.g. Christie et al., 2014). The Kichler (2013) study was the only one not to recruit from a paediatric diabetes team and stated participants were from a mental health clinical population. However recruitment was via a variety of methods, including advertising in non-mental health settings. There was also no attempt to operationalise what was meant by a clinical population or inclusion criteria to specifically capture this population.

Retention rates between baseline and post-treatment assessment ranged from 60% (Holmes et al., 2014) to 100% (Loding et al., 2008; Maranda et al., 2015). Three studies did not achieve over 70% retention rates. Potential attrition bias was also observed in a further three studies in that there were differences in attrition rates from randomisation to baseline assessment between intervention groups (Grey et al., 2009) and males and females (Newton & Ashley, 2013). In the Robling study (2012) there was a low completion rate for the psychosocial measures in particular.

4.3.4 Quality of intervention. Interventions were well described in the majority of studies or references were provided for further information. In three studies interventions were poorly described. For example, the multi-component intervention described by Mayer-Davis (2015) combined motivational interviewing (MI) and problem solving skills training with elements of behavioural family
systems therapy (BFST). It is unclear however which elements of MI or BFST were used within the intervention. More than half (n = 13) made some attempt to check fidelity. The risk of bias from omission of fidelity checks differed across studies. For example, in an online intervention fidelity checks were unnecessary as everyone received the same intervention provided they accessed the online content (Jaser, Patel, et al., 2014). However in the pet care intervention (Maranda et al., 2015) no attempts were made to objectively verify if young people undertook the tasks as instructed. It is therefore difficult to conclude that any observed effects could be attributed to the intervention.

4.3.5 Quality of analysis. The reporting of statistical analysis varied across studies with some providing more information than others. However all studies appeared to use an appropriate method of analysis for the study design and data collected. Fewer than half the studies (n = 10) carried out an intention to treat analysis. This is likely to have a larger impact where attrition at follow up was also high (i.e. Holmes et al., 2014; Newton & Ashley, 2013).

4.4 Aims of Interventions

A review of the studies identified only 11 of the studies outlined the main aims of the intervention. Three of these specifically stated improvements in QoL as an aim of the intervention (Christie et al., 2014; Grey et al., 2009; Jaser, Whittemore, et al., 2014). The Laffel (2003) study stated a maintenance in QoL as an aim while Kichler (2013) stated improvement in psychosocial functioning, although not specifically QoL. Glycaemic control was stated as an aim of the intervention in four studies (Holmes et al., 2014; Jaser, Patel, et al., 2014; Murphy et al., 2007; Robling et al., 2012). Adherence to treatment was also described as an aim in three studies.
(Holmes et al., 2014; Katz et al., 2014; Newton & Ashley, 2013). The Murphy (2007) study also specifically outlined shared responsibility of treatment as an aim of their structured education intervention.

Although not described as a main aim of the intervention, QoL was identified as a primary outcome of the evaluation in four studies (Loding et al., 2008; Price et al., 2016; Von Sengbusch et al., 2006; Waller et al., 2008) and as a secondary outcome in five studies (Channon et al., 2007; Maranda et al., 2015; Mayer-Davis et al., 2015; Murphy et al., 2012; Nansel et al., 2007). Neither the Wang (2010) nor the Graue (2005a) studies outlined the specific aims of their interventions or identified which of their outcomes were primary or secondary.

4.5 Intervention Effects

4.5.1 Reported Improvements. In total, eight studies reported significant beneficial effects on QoL outcomes. Two uncontrolled studies evaluating structured group education reported significant within group effects. Waller et al (2008) reported significant improvements in total scores on both the generic and diabetes-specific modules of the PedsQL at 6 month follow up. Similarly, von Sengbusch et al (2006) reported significant improvements in the diabetes-specific and self-esteem subscales at 6 month follow up. Two RCTs evaluating structured group education interventions also reported significant effects compared with a treatment as usual control. The Graue (2005a) study measured diabetes-specific QoL using the DQoL-Y. Improvements were observed for the impact subscale at 15 months follow up. The Price (2016) study measured generic and diabetes specific QoL using the Peds-QL. At 6 month follow up, significant effects were found for the generic physical, psychological and total QoL scores as well as the diabetes-specific symptoms
subscale. Improvements on the generic total scores were maintained at 12 months but not at 24 months. Significant effects were also found for the control group on the diabetes-specific adherence subscale at both 12 and 24 months compared with the intervention group.

Three RCT’s compared CST interventions in different formats; group-based for school aged children (Grey et al., 2009), online (Jaser, Whittemore, et al., 2014) and family-focussed (Holmes et al., 2014), with education interventions delivered in the same format. Diabetes-specific QoL was measured in the Grey (2009) and Holmes (2014) studies using the DQoL-Y and the PedsQL, respectively. The Jaser, Whittemore (2014) study measured generic QoL using the PedsQL. All three studies reported improved QoL outcomes over time for both groups however no group differences were found for any of the interventions. In the Grey (2009) study only improvements in the worry subscale were maintained over time. Jaser, Whittemore (2014) also employed a cross-over design. The study found that those who had participated in both online interventions had greater improvements on QoL outcomes than those participating in only one. Although the authors reported support for CST based on time effects the lack of a non-active control limits the conclusions that can be drawn about either intervention. The Channon (2007) study compared MI with supportive visits and measured diabetes-related QoL using the DQoL-Y. The authors reported significant effects of the MI intervention on all subscales of the DQoL-Y at 12 months on the impact and satisfaction subscales maintaining at 24 months.

4.5.2 Quality of Evidence. Many of the interventions studied were multi-component and in total there were eight different therapeutic elements evaluated as outlined in Table 1. The quality of the evidence of each element varied.
The most robust element investigated was coping skills training (CST) with a total of three studies including elements of CST all of which reported beneficial effects for QoL. Given these studies were all rated either acceptable or high quality in the quality review it would appear there is good evidence to conclude CST an effective intervention.

Structured education was the most widely studied therapeutic element in the included studies with 10 studies incorporating some education and over half of these being rated either acceptable or high quality. Of the six studies being rated as either acceptable or high quality only two reported beneficial results. On balance then it is difficult to conclude structured education to be effective in improving QoL in the paediatric diabetes population. However two of the studies who did report beneficial results evaluated the same group education intervention, specifically the KICK-OFF intervention. Although one of these studies was rated as low quality these results were later confirmed in a high quality study. It is possible this particular education intervention is effective where others are not.

Motivational Interviewing was an included therapeutic element in four studies, three of which were rated as acceptable or high quality. Yet only one of these studies reported beneficial effects of the intervention. Furthermore, two studies including MI elements, which were rated as acceptable and high quality, reported improvements for the control group when compared to the intervention group. There would therefore appear to be robust evidence that MI is not an effective intervention for improving QoL and may indeed be detrimental to QoL in this population.

Family teamwork interventions were explored in three of the included studies, two of which were rated as acceptable and one being rated as high quality.
Despite the robust nature of the studies only one of these reported beneficial effects on QoL. On balance then it would appear there is little evidence to conclude that family teamwork interventions are effective. In addition, although the Holmes et al. (2014) study reported beneficial effects this study also included elements of CST. It appears likely then that the improvements noted in this study could be attributed to the CST elements rather than the family teamwork elements.

There were a number of other therapeutic elements included in other interventions however the quality of the evidence of each made it difficult to draw any firm conclusions about the potential effectiveness of these. Behavioural and problem-solving elements were each evaluated in four studies. No studies reported evidence of effectiveness of either of these elements in improving QoL. However in each case, three out of the four studies were rated as low quality. Likewise, family therapy and peer support were each evaluated in two studies all of which were rated as low quality. Although there was no evidence presented in these studies for the effectiveness of any of these elements, the low quality of the evidence base makes it difficult to draw conclusions. It remains a possibility that higher quality studies could show these therapeutic elements to be beneficial in improving QoL in this population.

5. Discussion

The importance of health-related quality of life as a treatment outcome has been increasingly emphasised (Grey, 2012; Polonsky, 2002). This may be particularly the case in paediatric diabetes, where the burden of daily management of the condition can take a toll on children and parents (Davidson et al., 2004; Lindström et al., 2011). Evidence suggests many young people with type 1 diabetes
report lower HRQoL than their healthy peers (Varni, Burwinkle, Jacobs, et al., 2003). The aim of the current review was to identify any interventions that were aimed at improving HRQoL and to consider their effectiveness in children and adolescents with type 1 diabetes.

Previous systematic reviews have highlighted the lack of consideration of QoL outcomes in intervention trials (Couch et al., 2008; Pillay et al., 2015). The high number of studies identified in the current review, 20 of which were published in the last decade, suggests this is a trend which is changing. Despite this, only three of the studies reported improvement in HRQOL as a specific aim of the intervention being evaluated. This suggests that improvements in HRQOL are less considered in the development and planning of interventions. The most common reported aims of the interventions were improvements in treatment adherence and glycaemic control. The associations between treatment-related outcomes such as these and HRQOL are not consistent (Ingerski et al., 2010; Laffel, Connell, et al., 2003) and therefore interventions designed to target treatment-related outcomes may not be sufficient to translate into improvements in HRQOL. This may be the reason fewer than half the studies reported significant improvements in HRQOL outcomes.

Coping skills training (CST) has been extensively evaluated in the paediatric population by Grey and colleagues over the past 15 years with significant improvements in HRQOL across a number of treatment modalities, including group based (Grey et al., 2009), family based (Holmes et al., 2014) and online (Jaser, Whittemore, et al., 2014). All these studies were rated in the current review as either acceptable or high quality. Although firm conclusions about the effectiveness of CST was limited by the use of comparably effective control arms, based on the current review there is strong evidence to suggest that CST is an effective intervention for
improving HRQOL outcomes for children and young people who have type 1 diabetes.

There was also some evidence that structured diabetes education groups can be effective in improving HRQOL outcomes. In particular, the Kids in Control of Food (KICK-OFF) intervention, an intensive 5-day structured education group developed in the UK for adolescents with type 1 diabetes. The intervention was initially validated in an uncontrolled trial (Waller et al., 2008) and was later replicated in a high quality RCT (Price et al., 2016). Two other group education interventions reported significant HRQOL outcomes (Graue et al., 2005a; Von Sengbusch et al., 2006) however their designs were less robust.

The multi-modal nature of many of the interventions and the overlap of approaches between them made it difficult to assess which therapeutic elements contributed to the success of some but not others. There is some indication however that intensive education interventions delivered over a series of consecutive days can be effective (Price et al., 2016; Von Sengbusch et al., 2006; Waller et al., 2008). Other education interventions delivered less frequently and over a longer period did not promote HRQOL outcomes. It is possible the intensive format was perceived by participants as less intrusive than finding the time to attend group sessions on an ongoing basis. The exception to this is the Graue (2005a) study which was not delivered intensively however half the interventions sessions in this study were carried out individually online. This may have been perceived as less of a burden than attending more regular group sessions.

Although motivational interviewing (MI) was shown to be effective in the Channon (2007) study, this was not replicated in other studies using an MI approach,
including high quality RCTs (Christie et al., 2014; Nansel et al., 2007; Robling et al., 2012; Wang et al., 2010). Motivational interviewing is an intervention designed to motivate participants to move towards positive changes in behaviour (Miller & Rollnick, 2012). The primary aim of most of the MI-based studies reviewed was the achievement of optimal glycaemic control through improved treatment adherence. Conceptually, this may be insufficient to effect positive changes in HRQOL.

The lack of beneficial outcomes in family-focussed interventions was perhaps surprising given the associations between HRQOL and family functioning (Botello-Harbaum et al., 2008; Grey et al., 1998; Laffel, Connell, et al., 2003). The exception to this was Holmes et al (2014). This intervention combined elements of the family-focused intervention described in Laffel et al. (2003) with elements of CST. However there is strong support for the effective contribution of CST rather than the family-focussed elements given the lack of evidence for these elsewhere.

Despite the majority of the studies being rated either acceptable or high quality there were some limitations identified in the body of evidence that should be taken into consideration. Intention to treat analyses were not undertaken in many studies meaning there is less confidence in some of the effects, especially those where there is high risk of attrition bias (e.g. Holmes et al., 2014). In addition, less than half the studies achieved a sample size necessary to detect a medium effect size. It is possible that with a sufficient sample size significant improvements in HRQOL may be observed in other interventions. This may be the case for the family focussed interventions, few of which achieved a sufficient sample size. Future studies would benefit from larger sample sizes and a more rigorous approach to the management of missing data in the analysis.
Although many treatment targets (e.g. family communication, shared responsibility for treatment, self-efficacy) of the reviewed studies have been shown to be associated with HRQOL in this population there was little consideration of these associations within a theoretical framework. Grey and colleagues (Grey et al., 2009; Holmes et al., 2014; Jaser, Whittemore, et al., 2014) on the other hand described a conceptual framework based on a stress-adaptation model (Pollock, 1986) that outlined a process of adaptation specifically for a paediatric diabetes population, of which HRQOL was an integral component. This theoretically driven approach, along with a rigorous approach to evaluation, seems to be promising in promoting improved HRQOL for young people with type 1 diabetes.

There are some limitations within the current review that should be borne in mind when considering the findings. Firstly, the review did not include a search of grey literature. It is possible that this could have introduced a publication bias to the findings. A previous meta-analysis has shown that published studies can show larger intervention effects than non-published trials (Hopewell, 2007). It is possible this has been case in the current review. However it should also be noted that many of the studies reported in the current review did not report positive intervention effects in relation to QoL suggesting a trend for publication of intervention trials even in the absence of beneficial findings. Finally, the review included both controlled and uncontrolled studies. Previous reviews had concluded there were few intervention trials investigating QoL outcomes. The current review included uncontrolled trials to ensure a wide coverage of the literature and highlight promising areas for future research however this also introduces the possibility of reducing the quality of studies included the review. Uncontrolled studies were subjected to the same quality
review as controlled studies to ensure any conclusions reached were in the context of the quality of the evidence presented.

6. Conclusion

Overall, the reviewed studies suggest there is increasing attention being paid to HRQOL outcomes in the clinical trials, some of which have proved to be effective. There is less evidence however that HRQOL is being considered in the design of interventions. Future interventions would benefit from a more theoretical approach to development supplemented by rigorous validation in large samples. However there is promising evidence that psychological interventions can improve HRQOL outcomes in children and adolescents with type 1 diabetes.

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Chapter 2

An exploration of the role of psychological flexibility, mindfulness and parenting in predicting health outcomes in adolescents with type 1 diabetes.

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Abstract

**Purpose:** The current study was designed as an initial exploration of the associations between psychological flexibility, mindfulness and, parenting behaviours with diabetes-related outcomes (specifically quality of life and treatment adherence).

**Methods:** Forty five adolescent-parent dyads were recruited via paediatric diabetes clinics and asked to complete a number of questionnaires measuring the study variables.

**Results:** Although parenting behaviours were associated with health outcomes these constructs lost their predictive value when considered in the context of psychological flexibility and mindfulness. In regression analyses only parent and adolescent diabetes-specific psychological flexibility predicted treatment adherence while adolescent mindfulness and insulin administration predicted quality of life.

**Conclusions:** Psychological flexibility and mindfulness seem to be useful constructs for understanding health outcomes in adolescents with type 1 diabetes suggesting acceptance and commitment, and mindfulness-based therapies may be beneficial for improving outcomes in this population. Further research would be beneficial in elucidating these relationships further.

**Keywords**

Type 1 diabetes, Psychological flexibility, mindfulness, parenting, adolescence.
Highlights

- The associations between psychological flexibility, mindfulness, parenting and health outcomes were examined.

- Parental care was associated with improved outcomes while parental control was associated with poorer outcomes.

- Psychological flexibility and mindfulness were associated with better outcomes.

- Treatment adherence was predicted by parent and adolescent diabetes-specific psychological flexibility.

- Quality of life was predicted by adolescent mindfulness and insulin administration.
1. Introduction

The transition to adolescence can be a challenging time for all young people as they face a number of developmental tasks. Living with a serious illness, such as type 1 Diabetes (T1D) can further complicate this period and place additional stresses on both the young person and their parents (Davidson, Penney, Muller, & Grey, 2004; Whittemore, Jaser, Chao, Jang, & Grey, 2012). The treatment regime for T1D involves multiple components of lifestyle and medication management and complex decision-making about the need to adjust insulin doses according to blood glucose levels and dietary intake (National Institute for Health and Care Excellence [NICE], 2015; Diabetes Control and Complications Trial Research Group [DCCT], 1993). The consequences of sub-optimal glycemic control can be serious and life-threatening (Currie et al., 2013; Nathan, 1993). Worryingly, the adolescent period is often characterised by poor adherence to treatment and glycaemic control as well as problems in psychosocial adjustment (Ashraff, Siddiqui, & Carline, 2013; Levine et al., 2001; Mortensen & Hougaard, 1997) and can persist into adulthood (Bryden et al., 2001).

Recent studies in adult populations have implicated constructs such as psychological flexibility and mindfulness as potential predictors of psychological adjustment, quality of life (QoL) and self-management in health conditions, including chronic pain (McCracken & Velleman, 2010), substance misuse (Luoma, Kohlenberg, Hayes, Bunting, & Rye, 2008) and obesity (Lillis, Hayes, Bunting, & Masuda, 2009). A randomised clinical trial for treatment of type 2 diabetes found better improvements in self-management following acceptance and mindfulness training compared with diabetes education. (Gregg, Callaghan, Hayes, & Glenn-
Furthermore, these improvements were mediated by changes in acceptance-based coping.

Mindfulness and psychological flexibility are related but distinct constructs emphasised in functional contextual behavioural theories of psychological well-being. Psychological flexibility is defined as “the ability to fully contact the present moment and the thoughts and feelings it contains without needless defense, and, depending upon what the situation affords, persisting or changing in behavior in the pursuit of goals and values” (Bond et al., 2011, p. 678). This can be contrasted with psychological inflexibility which results from psychological processes including experiential avoidance and cognitive fusion (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). Cognitive fusion is a psychological process where individuals mistake internal psychological events (e.g. thoughts, images, emotions) as being direct representations of present reality and then over-identify, or “fuse” with them (Hayes et al., 2006). Experiential avoidance relates to an individual’s tendency to attempt to control or change internal events rather than fully experiencing them in the present moment (Hayes et al., 2006). Together, cognitive fusion and experiential avoidance can undermine an individual’s capacity to act in accordance with their goals or values and result in psychological inflexibility (Hayes et al., 2006).

Mindfulness is conceptualized as a mental mode that facilitates psychological flexibility (Hayes et al., 2006) by increasing the capacity for meta-cognitive reflection, the ability to shift attention and awareness and the development of a non-judgmental and accepting attitude to internal and external events (Kabat-Zinn, 1994). Mindfulness allows for reflection on the self-construction of reality while retaining awareness of external stimuli (Kabat-Zinn, 1994). The cultivation of mindfulness can facilitate cognitive and behavioural flexibility as behavioural response can be based
on an appraisal of the entire context rather than being reactive to a limited appraisal of internal events (Bishop et al., 2004).

In community samples, lower levels of psychological flexibility and mindfulness have been shown to be related to poor outcomes for adolescents, including somatic complaints, internalizing and externalizing problems and QoL (Greco, Baer, & Lambert, 2008; Greco, Baer, & Smith, 2011). In addition, adolescents with higher dispositional mindfulness have been shown to be less likely to engage in health-risk behaviours than those with lower dispositional mindfulness (Black, Sussman, Johnson, & Milam, 2012).

Regarding young people with T1D, it has been shown that a strong self-identification with illness is associated with negative beliefs about diabetes and poor health outcomes (Griva, Myers, & Newman, 2000). Recently, Hadlandsmyth, White, Nesin & Greco (2013) proposed that a strong illness identity could be conceptualised as cognitive fusion with the associated negative beliefs likely leading to discomfort. They further suggest an individual may act to reduce or avoid this discomfort by engaging in behaviours that may undermine their treatment adherence and lead to sub-optimal metabolic control. Avoidant coping styles tend to be related to poor adherence to treatment, sub-optimal glycemic control and lower QoL while proactive coping styles tend to be related to improved outcomes (Jaser & White, 2011). Hadlandsmyth et al. (2013) propose this could be suggestive of experiential avoidance as unhelpful coping strategies are used to avoid distressing diabetes-related cognitions. However, no published studies have explored these constructs and their relationship with diabetes-related outcomes.

The complexities of diabetes treatment mean parents play a key role in successful management of the condition throughout childhood and adolescence.
Given the important role of parents it is also possible that parental psychological flexibility and mindfulness may be an important influence on the way diabetes is managed within the family. There is growing evidence that the nature of parental involvement is crucial in understanding self-care in adolescence. A number of studies have demonstrated that responsive parenting, characterised by warm and caring parental behaviours lead to both improved QoL and increased self-care behaviours in children and adolescents (Botello-Harbaum, Nansel, Haynie, Iannotti, & Simons-morton, 2008; Faulkner & Chang, 2007; Whittemore, Urban, Tamborlane, & Grey, 2003). Conversely, parental behaviours perceived by the adolescent as controlling or over-protective are related to poorer outcomes (Graue, Wentzel-Larsen, Hanestad, & Sovik, 2005; Wiebe et al., 2005). For example, in a sample of adolescents aged 11-18 years, adolescents who perceived their parents as controlling were more likely to have poorer health-related QoL (Graue et al., 2005). In a slightly younger sample of 10-15 years, the perception of controlling involvement, as opposed to perceived supportive involvement, was related to poorer self-rated adherence and QoL, regardless of actual level of involvement (Wiebe et al., 2005).

The ways in which parents interact with their children are likely to be influenced by their own levels of psychological flexibility and mindfulness. Anderson and Coyne, 1991) introduced the concept of “miscarried helping” to describe a process whereby parents of chronically ill children engage in well-intentioned but excessive or inappropriate behaviours to manage their child’s health, which inadvertently conflict with the child’s developmental need for autonomy and independence, which leads to poorer health outcomes. In a study of children with T1D, parental over-protectiveness was related to parents’ perception of their child as
vulnerable (Mullins et al., 2004). Further, this was the case regardless of their child’s actual health status. This “miscarried helping” could be suggestive of low levels of psychological flexibility whereby the parents persist in their behaviour (i.e. inappropriate control and over-protectiveness) in reaction to internal events (i.e. beliefs about what is helpful) with limited awareness of external stimuli (i.e. the child’s developmental needs and actual health status). A parent with high traits of mindfulness and psychological flexibility may have better capacity to reflect on their internal experiences (e.g. fear of complications) and yet take account of their child’s developmental needs for autonomy in their interactions with their child. This may lead to a parent displaying warm and caring behaviours towards their children despite the distress associated with diabetes-related cognitions. In this way, it is possible that parental mindfulness and psychological flexibility may also be associated with health-related outcomes for adolescents with diabetes.

2. Aims

The current study was designed as an initial exploration of the associations between psychological flexibility and mindfulness, parenting behaviours and diabetes-related outcomes, specifically quality of life and treatment adherence. It was hypothesised that:

1. Adolescent psychological flexibility and mindfulness would be associated with improved health-related outcomes.

2. Parent psychological flexibility and mindfulness would be associated with higher levels of parental care and lower levels of parental control.

3. Parent psychological flexibility and mindfulness would be associated with improved health-related outcomes in adolescents.
4. High levels of parental care and lower levels of parental control would be associated with improved health-related outcomes in adolescents.

3. Methods

3.1 Design

The study used a cross-sectional, quantitative design. All variables were measured by self-report questionnaires completed by young people and parents.

3.2 Participants

Participants were adolescents, and their parent, under the care of paediatric diabetes teams across five areas of Scotland. Eligibility criteria for the study were: young people aged 12-18 year olds, diagnosed with type 1 Diabetes (T1D) for at least 1 year, literate and fluent in English to an extent to allow them to complete the questionnaires. Potential participants were excluded if they had a co-morbid diagnosis of a developmental disorder or other chronic illness unrelated to diabetes. Parents were recruited where they were a primary caregiver for the young person, regardless of whether this was the mother or father.

3.3 Procedure

Potential participants were initially provided with a study information sheet (Appendix E) from the diabetes team either in person at a routine outpatient appointment or by post. The researcher then attended subsequent outpatient clinics. Where an adolescent and their parent expressed interested in participating, written consent was sought from both the adolescent and parent (Appendix F). Adolescents and parents were then asked to complete a series of self-report measures (Appendix H). Participants were given the option of completing the questionnaires at the clinic
or at home. Paper copies and online versions of the measures were available depending on participant preference.

Where attendance at clinics was not possible, potential participants were sent the information sheet, consent form and questionnaire in the post. Those who were interested in participating were asked to complete the consent form and measures and were provided with a stamped addressed envelope to return them direct to the researcher. An online version was also made available to provide an alternative means of participation.

Ethical approval for the study was given by the NHS Research Ethics Committee (Appendix G).

3.4 Measures Completed by Adolescents

A general and a diabetes-specific measure of adolescent psychological inflexibility was used in the current study. This reflects findings that general acceptance and condition specific acceptance appear to account for different levels of variance in condition specific outcomes (McCracken & Zhao-O'Brien, 2010).

3.4.1 Acceptance and Fusion Questionnaire – Youth 8 (AFQ-Y8; Greco et al., 2008). The AFQ-Y8 is an eight item measure of psychological inflexibility, scored on a 5 point Likert-type scale asking respondents to indicate how true each item is for them, ranging from 0 (not at all true) to 4 (very true). To obtain a score reflecting psychological flexibility, rather than inflexibility, all items were reversed scored. Item scores were then summed to provide an overall score for psychological flexibility, ranging from 0 – 32, with higher scores indicating more psychological flexibility. The AFQ-Y8 has been found to have good internal consistency with
alpha coefficients of 0.82 in samples of 10 -17 year olds (Greco et al., 2008). In the current sample $\alpha = 0.81$.

**3.4.2 Diabetes Acceptance and Action Scale (DAAS; Greco & Hart, 2005).** The DAAS is a 42 item measure of psychological flexibility directly related to diabetes management in children and adolescents. Adolescents were asked to rate how often each item is true for them on a 5 point Likert-type scale, ranging from 0 (never true) to 4 (always true). Item scores were summed to provide an overall score for diabetes-related psychological flexibility, with scores ranging from 0 – 168, with higher scores indicating more diabetes-related psychological flexibility. Preliminary data has suggested that scores on the DAAS are correlated with diabetes related QoL, diabetes-related worry and adherence to medical regime ($r = .36$, .41 and .30, respectively; (Ciarocchi & Bilich, 2006). In the current sample $\alpha = 0.91$.

**3.4.3 Child and Adolescent Mindfulness Measure (CAMM; Greco et al., 2011).** The CAMM is the only measure to provide a developmentally sensitive measure of mindfulness specifically for children and adolescents. It presents 10 items asking participants to rate how often each item is true for them. Items are scored on a 5 point Likert-type scale, ranging from 0 (never true) to 4 (always true). As all items are negatively worded they are reversed scored and scores summed to provide an overall measure of mindfulness, with scores ranging from 0 – 40, with higher scores indicating more mindfulness. The measure has been found to have good internal consistency with an alpha coefficient of 0.8 in samples aged 10-17 years and confirmatory analysis has supported the single factor structure in this population (de Bruin, Zijlstra, & Bögels, 2013; Greco et al., 2011). In the current sample, $\alpha = 0.89$. 
3.4.4 Parental Bonding Instrument – Brief Current (PBI-BC; Klimidis, Minas, & Ata, 1992). The PBI-BC is an adapted version of the Parental Bonding Instrument (PBI; Parker, Tupling, & Brown, 1979) which was developed to measure adult’s perceptions of their parenting experience across two subscales; care and control. The PBI-BC was adapted to measure adolescent’s perception of parenting over the previous 3 months. The care subscale contains four items relating to the adolescent’s perception of how warm and caring their parents are. The control subscale contains four items relating to adolescent’s perception of parental control. Adolescents are asked to rate how similar each item is to their parent on a 3 point Likert-type scale, ranging from 1 (never) to 3 (usually). Items scores are summed to provide an overall score for each subscale, ranging from 4 – 12, with higher scores indicating the perception of either higher levels of care or control. The PBI-BC has been found to have adequate internal consistency with Cronbach’s alphas ranging from 0.72 to 0.8 depending on the dimension and parent being rated (Klimidis et al., 1992). In the current sample the subscale had $\alpha = 0.69$ for the care sub-scale and $\alpha = 0.60$ for the control scale.

3.4.5 Diabetes Quality of Life for Youth – Short Form (DQoLY-sf; Skinner, Hoey, McGee, & Skovlund, 2006). The DQoLY-sf is a 22- item questionnaire measuring four subscales of QoL specific to diabetes; impact of disease (11 items), diabetes-related worry (7 items), parent issues (3 items), and health perception (1 item). All items, except the health perception item, asks adolescents to rate how often the item relates to them on a 5 point Likert-type scale, ranging from 0 (never) to 4 (all the time). The health perception item provides a 4 point scale, ranging from 1 (excellent) to 4 (poor). Scores for all items were summed to provide an overall QoL score, ranging from 1 – 88, with higher scores indicating
poorer QoL. The measure has been validated in a large-scale, multinational sample of 2077 young people aged 10-18 years, finding adequate to good internal consistency, ranging from 0.63 to 0.86 across countries (Skinner et al., 2006). In the current sample $\alpha = 0.87$.

3.4.6 Self Care Inventory (SCI; La Greca, 1992). The SCI is a 15 item self-report measure of the behaviours associated with a typical T1D treatment regime including monitoring glucose levels, insulin administration, physical activity and monitoring of food intake. Adolescents are asked to rate how often they have adhered to recommended treatment tasks in the last 2 weeks on a 5 point Likert-type scale, ranging from 1 (never) to 5 (always). The authors recommend only seven item scores are used to calculate the overall adherence scale (items 1, 2, 5, 6, 7, 8 and 13). Scores on these seven items were summed to obtain an overall score for treatment adherence, ranging from 7 to 35, with higher levels indicating better adherence to recommended treatment. The items have been designed to be relevant for different regimes, for example insulin pumps or injections. The measure has been shown to have adequate internal consistency for adolescent report with an alpha coefficient of 0.72 (Lewin et al., 2009). In the current sample $\alpha = 0.77$.

3.5 Measures Completed by Parents

3.5.1 Five Factor Mindfulness Questionnaire – Short Form (FFMQ-sf; Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011). The FFMQ-sf measures five facets of mindfulness across 24 items; observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience, rated on a 5-point Likert-type scale, ranging from 1 (never or very rarely true) to 5 (very often or always true). An overall mindfulness score was computed by
summing the scores for all items. Scores range from 24 – 120, with a higher score indicating more mindfulness. The FFMQ-sf has been shown to have good validity and reliability (Bohlmeijer et al., 2011). In the current sample Chronbach’s α = 0.73.

3.5.2 Acceptance and Action Questionnaire – II (AAQ-II; Bond et al., 2011). The AAQ-II is a seven item self-report measure of psychological inflexibility. Items are scored on a 7-point Likert-type scale with respondents asked to rate how true each item is for them, ranging from 1 (never true) to 7 (always true). To obtain a score reflecting psychological flexibility rather than inflexibility, all items were reversed scored. An overall score for psychological flexibility was computed by summing the scores of all items. Scores range from 7 – 49, with higher scores indicating higher level of psychological flexibility. The measure has been found to have good validity and reliability across different populations (Bond et al., 2011). In this sample α = 0.91.

3.5.3 Demographic Questionnaire. Parents were also asked to complete a short questionnaire collecting data in relation to demographics, including age, sex and ethnicity of adolescent and parent, relationship to the child and socio-economic status. Socio-economic status (SES) was determined using the National Statistics Socio-Economic Classification (NS-SEC; Office for National Statistics, 2010).

Information relating to the adolescent’s diabetes was also collected including age at diagnosis, type of insulin delivery and an estimate of the child’s HbA1c level at their last outpatient appointment.

3.6 Analysis

All analysis was undertaken using the SPSS package. Exploratory analysis of the raw data was undertaken to analyse missing values using Little’s Missing
Completely At Random (MCAR) test, which was non-significant, indicating missing values were MCAR. Estimation Maximisation (EM) was used to impute missing data. EM has been shown to be an acceptable method of dealing with missing data with up to 50% missingness when data is MCAR (Scheffer, 2002). In the current sample, no more than 7% of data was missing for each variable.

Descriptive statistical analysis was undertaken for all variables. Descriptive statistics reported are mean and standard deviations for continuous variables and count and percentage for categorical variables unless otherwise specified.

Independent samples t-tests were used to examine differences between adolescents who participated with a mother and father as well as differences between those using injections and an insulin pump. Where there was a difference between the groups on any primary outcome the variable was entered into the subsequent regression analysis as a potential covariate.

Correlation analysis was used for an initial exploration of all continuous variables. Finally, two regression analyses were undertaken to explore which variables predicted the outcome variables; adherence to treatment and QoL. Any variables identified in the correlational analysis as significantly related to the outcome variables were entered into the regression analyses as potential covariates. An assessment of the assumptions of the regression analysis was also undertaken (see Appendix I for a full outline).

The GPower (Faul, Erdfelder, Lang, & Buchner, 2007) software package was used to provide a power calculation for a linear multiple regression model with 11 predictors. This showed a sample of 59 or 123 would be required to detect a large ($f^2 = 0.35$) or medium ($f^2 = 0.15$) effect size, respectively, at $p \leq 0.05$ and 80% power.
4. Results

A total of 94 young people and their parent were approached to take part in the study. Of these, 59 agreed to participate. In 10 of these dyads only the young person’s data were collected, in three cases only parents were collected and in a further case the young person failed to complete the full outcome measures. These 14 dyads were excluded from the analysis leaving a total of 45 included. Only 38 parents provided an estimate of their child’s HbA1c level.

Table 1. Demographic and clinical characteristics of adolescents and parents (n = 45).

<table>
<thead>
<tr>
<th></th>
<th>Mean (standard Deviation)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Young Person</td>
<td>15.47 (1.47)</td>
<td>12 – 18</td>
</tr>
<tr>
<td>Parent</td>
<td>45.76 (4.76)</td>
<td>36 – 55</td>
</tr>
<tr>
<td>Age at diagnosis</td>
<td>9.80 (3.67)</td>
<td>1 – 16</td>
</tr>
<tr>
<td>Duration since diagnosis</td>
<td>5.67 (3.69)</td>
<td>1 – 14</td>
</tr>
<tr>
<td>HbA1c (n = 38)</td>
<td>6.84 (1.26)</td>
<td>4.3 – 10.6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>21</td>
<td>46.7%</td>
</tr>
<tr>
<td>Male</td>
<td>24</td>
<td>53.3%</td>
</tr>
<tr>
<td>Insulin Administration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection</td>
<td>34</td>
<td>75.6%</td>
</tr>
<tr>
<td>Pump</td>
<td>11</td>
<td>24.4%</td>
</tr>
<tr>
<td>Parent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td>38</td>
<td>84.4%</td>
</tr>
<tr>
<td>Father</td>
<td>7</td>
<td>15.6%</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>44</td>
<td>97.8%</td>
</tr>
<tr>
<td>Eurasian</td>
<td>1</td>
<td>2.2%</td>
</tr>
<tr>
<td>SES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Managerial/Professional</td>
<td>24</td>
<td>53%</td>
</tr>
<tr>
<td>Intermediate/Low</td>
<td>14</td>
<td>31.1%</td>
</tr>
<tr>
<td>Supervisory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Semi-routine/Routine</td>
<td>7</td>
<td>15.5%</td>
</tr>
</tbody>
</table>

Note. Age and Duration since diagnosis presented in years.
4.1 Demographic and Clinical Characteristics

The demographic and clinical characteristics of the sample are provided in Table 1. Independent samples t-tests revealed that young people whose father participated reported significantly lower diabetes psychological flexibility than those whose mother participated (M = 141.57 vs. 119.34, t = -2.956, p = 0.005). This result may be due to the fact that there were fewer fathers than mothers (n = 7 vs. 38). However it is also possible that diabetes psychological flexibility in young people may vary depending on whether their father is more or less involved in their treatment. Young people who administered insulin by pump reported poorer QoL than those who administered via injections (M = 20.38 vs 28.18, t = 2.070, p = 0.51). Although this fell just short of statistical significance. Both variables were retained and included in the regression analyses.

4.2 Correlation Analysis

Table 2 shows the means and bivariate correlation coefficients for the demographic, clinical and primary study outcomes.

4.2.1 Demographic and clinical variables. Correlation analyses revealed that young people tended to report higher diabetes psychological flexibility when their parents were older (r = 0.315, p = 0.035) and reported higher SES (r = -0.298, p = 0.047). Younger adolescents were more likely to report adhering to their treatment than older adolescents (r = -0.317, p = 0.03) however increasing parental age was also associated with better adherence (r = 0.372, p = 0.012). In addition, better adherence to treatment was associated with lower HbA1c levels (r = -0.493, p = 0.002). Given adherence to treatment has been shown to be predictive of lower blood glucose levels this suggests the SCI was a good measure of treatment adherence in this sample.
Table 2. Means and significant correlations among demographic, clinical and primary outcomes (n = 45).

<table>
<thead>
<tr>
<th>Variable (Mean)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - Ad P/F (23.61)</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 - Diabetes P/F (122.63)</td>
<td>.545** (.000)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 - Ad M/F (29.34)</td>
<td>.475** (.001)</td>
<td>.562** (.000)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 – Adherence (28.36)</td>
<td>.539** (.000)</td>
<td>.657** (.000)</td>
<td>.490** (.001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>5 – Care (10.72)</td>
<td>.472** (.001)</td>
<td>.452** (.002)</td>
<td>-</td>
<td>.503** (.000)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 – Control (6.29)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>.328* (.028)</td>
<td>-</td>
<td>.305* (.042)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 – QoL (22.22)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>.419** (.004)</td>
<td>-</td>
<td>.496** (.001)</td>
<td>-</td>
<td>.623** (.000)</td>
<td>-</td>
<td>.396** (.007)</td>
</tr>
<tr>
<td>8 - Parent M/F (79.51)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>.304* (.042)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>.348* (.019)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 - Parent P/F (40.47)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>.390** (.008)</td>
<td>-</td>
<td>.427** (.003)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>.331* (.026)</td>
</tr>
<tr>
<td>10 - HbA1c* (6.84)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>.474** (.003)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>11 - Parent age (45.76)</td>
<td>-</td>
<td>.315* (.035)</td>
<td>-</td>
<td>.372* (.012)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>12 - Ad age (15.47)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>.323* (.030)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>13 – SES (3.0)</td>
<td>-</td>
<td>-.317* (.034)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-.487** (.001)</td>
</tr>
</tbody>
</table>

Note. Ad (Adolescent), P/F (Psychological Flexibility), M/F (Mindfulness), QoL (Quality of life), SES (Socio-economic status). * n = 38.

Pearson correlation co-efficient (p-value). * p<0.05 ** p<0.01
4.2.2 Psychological flexibility and mindfulness. Adolescent mindfulness was associated with both generic (r = 0.475, p = 0.001) and diabetes-specific psychological flexibility (r = 0.562, p < 0.001). Adolescents were also more likely to report higher mindfulness when their parents were higher in psychological flexibility (r = 0.390, p = 0.008). Psychological flexibility in both adolescents (r = -0.419, p = 0.004) and parents (r = -0.331, p = 0.026) was associated with improved QoL, as well as treatment adherence (adolescent; r = 0.539, p < 0.001, parent; r = 0.427, p = 0.003). Parent (r = -0.348, p = 0.019) and adolescent (r = -0.623, p < 0.001) mindfulness were also associated with improved QoL however only adolescent mindfulness was associated with treatment adherence (r = 0.490, p = 0.001).

4.2.3 Parental care and control. Parents who were perceived by their children as more warm and caring were more likely to be mindful (r = 0.304, p = 0.042) and to have children who were psychologically flexible (generic; r = 0.472, p = 0.001, diabetes; r = 0.452, p = 0.002). Adolescents were also more likely to stick to their treatment plan (r = 0.503, p > 0.001) and to report higher QoL (r = -0.349, p = 0.019) when they perceived their parent to be warm and caring.

Adolescents’ perception of parental control was not related to either adolescent or parent psychological flexibility or mindfulness. However those who perceived their parents to be more controlling also reported being less likely to stick to their treatment plan (r = -0.328, p = 0.028) and to have poorer QoL (r = 0.311, p = 0.038).

4.3 Regression Analysis.

All assumptions for a regression analysis were met (for more information see Appendix I).
4.3.1 Treatment adherence. Adolescent mindfulness and psychological flexibility (generic and diabetes-specific), parent psychological flexibility, parental care and control, along with age (adolescent and parent), participating parent, insulin administration and SES, were entered into a stepwise regression analysis to predict treatment adherence. Table 3 shows the raw and standardised regression coefficients, standard errors, confidence intervals and significance values for the predictors at each step. The final prediction model consisted of only two significant predictors: diabetes psychological flexibility and parent psychological flexibility, and was achieved in two steps with no predictors removed. This model was statistically significant, F (2, 42) = 25.428, p < 0.001, and accounted for 55% of the variance in treatment adherence (R² = 0.548, adjusted R² = 0.526). Diabetes psychological flexibility received a stronger weight (Beta = 0.610) in the model than parent psychological flexibility (Beta = 0.344).

Table 3. Regression model parameters predicting treatment adherence (n = 45).

<table>
<thead>
<tr>
<th>Step</th>
<th>Unstandardised Regression Co-efficient</th>
<th>Standardised Regression Co-efficient</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b (95% CI)</td>
<td>Standard Error</td>
<td>β</td>
</tr>
<tr>
<td>Step 1 (R² = 0.43, p &lt; 0.001)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes Psych/Flex</td>
<td>0.15 (0.1, 0.2)</td>
<td>0.26</td>
<td>0.66</td>
</tr>
<tr>
<td>Step 2 (R² = 0.55, p = 0.001)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes Psych/Flex</td>
<td>0.14 (0.09, 0.18)</td>
<td>0.02</td>
<td>0.61</td>
</tr>
<tr>
<td>Parent Psych/Flex</td>
<td>0.21 (0.08, 0.34)</td>
<td>0.07</td>
<td>0.34</td>
</tr>
</tbody>
</table>

Note. 95% CI (95% Confidence Interval), Psych/Flex (Psychological Flexibility).
4.3.2 Quality of life. Adolescent and parent mindfulness and psychological flexibility (generic and diabetes-specific), parental care and control, along with parent age, participating parent, SES and insulin administration, were entered into a stepwise regression analysis to predict quality of life. Table 4 shows the raw and standardised regression coefficients, standard errors, confidence intervals and significance values for the predictors at each step. The prediction model consisted of only two significant predictors; adolescent mindfulness and insulin administration, and was achieved in two steps with no predictors removed. This model was statistically significant, F (2, 42) = 18.132, p <0.001, and accounted for 46% of the variance in QoL (R^2 = 0.463, adjusted R^2 = 0.438). Quality of life was primarily predicted by adolescent mindfulness, which received the strongest weight (Beta = -0.615) in the model compared with insulin administration (Beta = 0.275).

**Table 4.** Regression model parameters predicting quality of life (n = 45).

<table>
<thead>
<tr>
<th></th>
<th>Unstandardised Regression Co-efficient</th>
<th>Standardised Regression Co-efficient</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b (95% CI)</td>
<td>Standard Error β</td>
<td>p</td>
</tr>
<tr>
<td>Step 1 (R^2 = 0.39, p &lt; 0.001)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adolescent Mindfulness</td>
<td>-0.9 (-1.24, -0.55)</td>
<td>0.17</td>
<td>-0.62</td>
</tr>
<tr>
<td>Step 2 (R^2 = 0.46, p &lt; 0.001)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adolescent Mindfulness</td>
<td>-0.89 (-1.21, -0.56)</td>
<td>0.16</td>
<td>-0.62</td>
</tr>
<tr>
<td>Insulin Administration</td>
<td>7.04 (1.2, 12.9)</td>
<td>2.9</td>
<td>0.28</td>
</tr>
</tbody>
</table>

Note. 95% CI (95% Confidence Interval).
5. Discussion

The purpose of the present study was to present an initial exploration of the relationships between psychological flexibility, mindfulness, parenting and diabetes outcomes. The correlational analysis confirmed many of the study hypotheses. As expected higher levels of both adolescent and parent psychological flexibility and mindfulness were related to positive outcomes for young people, in terms of both adherence to treatment and QoL. Contrary to expectations, parental care and control were unrelated to parent psychological flexibility, although parents who were high in mindfulness were more likely to be perceived by their children as warm and caring. Despite this, there was evidence that parental care and control were associated with diabetes outcomes, in that parental care was related to improved outcomes while parental control was associated with poorer outcomes. However when all variables were considered in conjunction in a multiple regression analysis, only adolescent diabetes-specific psychological flexibility and parent psychological flexibility were significant predictors of adherence to treatment, while adolescent mindfulness and insulin administration were significant predictors of QoL.

The current literature has been mixed with regards to the relationship between adherence to treatment and QoL with some showing these outcomes are related (Hilliard, Mann, Peugh, & Hood, 2013; Matziou et al., 2011) and others finding they are unrelated (Ingerski, Laffel, Drotar, Repaske, & Hood, 2010; Laffel, Connell, et al., 2003). In the current study better treatment adherence was associated with higher QoL. However the differential predictors of adherence to treatment and QoL suggest different mechanisms leading to these outcomes. Health-related QoL is an individual’s perception of the impact of a condition on physical, psychological and social functioning and is therefore fundamentally a subjective internal construct.
The intrusive and intensive nature of diabetes treatment mean it is likely to interrupt many different domains of a young person’s life (Polonsky, 2002). Indeed, in general, young people with diabetes report poorer QoL than healthy young people (Varni, Burwinkle, Seid, & Skarr, 2003). However the finding that adolescent mindfulness predicted QoL suggests that those young people with high traits of mindfulness may have capacity to experience these interruptions in a non-judgmental way resulting in positive benefits in their overall well-being, as measured by QoL.

In the current sample, those young people who received subcutaneous insulin infusion (i.e. insulin pump) reported poorer QoL than those who received insulin via injections, although this did not reach statistical significance. Insulin administration remained a significant predictor of QoL when all other variables were held constant, although it did only account for a modest level of the variance in QoL in the model. This is perhaps surprising given previous studies have found using an insulin pump to have a positive impact on QoL (Ingerski, Modi, et al., 2010; Lawrence, 2011). It is unclear why this discrepancy was evident in the current sample however may be due to the small number of participants using a pump compared with those receiving insulin through injections.

While there is overlap in the constructs of mindfulness and psychological flexibility, a core concept of psychological flexibility is the ability to commit to action in the direction of values and goals (Hayes et al., 2006). Treatment adherence is primarily concerned with committed action towards health-related goals. In adolescence, treatment adherence can be impacted by a number of psychological factors, such as depression (Hood et al., 2006), self-efficacy (Griva et al., 2000) and beliefs about effectiveness of treatment (Glasgow, Hampson, Strycker, & Ruggiero,
The finding in this study that diabetes specific psychological flexibility was the best predictor of treatment adherence highlights the importance in action towards diabetes-related goals despite the psychological difficulties this may pose. Parental perceptions of their child’s illness and the distress associated with this have also been shown to impact on the ways in which they interact with their child leading to reduced adherence to treatment (Butler et al., 2008; Carpentier, Mullins, Wolfe-Christensen, & Chaney, 2008; Mullins et al., 2004). The current findings suggest parents who are psychologically flexible may be better able to accept these internal experiences and yet act in accordance with their values, for example their child’s health needs.

In line with the current study it has typically been found that warm and caring parenting leads to improved outcomes (Botello-Harbaum et al., 2008; Faulkner & Chang, 2007; Whittemore et al., 2003) while parental control can lead to poorer outcomes (Graue et al., 2005; Wiebe et al., 2005) for young people. However the current study extends these findings by showing that when considered within the context of psychological flexibility and mindfulness, parenting factors lose their predictive value in determining outcomes for young people.

Given the association in the current study between parental care and adolescent psychological flexibility it is possible that adolescent psychological flexibility acts as a mediator between parental care and diabetes related outcomes. For example, parents who are warm and caring may facilitate the development of psychological flexibility in their children increasing their capacity to cope with the difficulties of managing diabetes. Alternatively, young people who are more psychologically flexible may have the capacity to be more accepting of the distress associated with a less caring parent while continuing to act in a way that is consistent
with their overall goals (i.e. good health outcomes). The exploratory nature of this study and the small sample size did not allow for mediational analysis to be carried out however this could be a promising area for further study in a larger sample size.

The recognition that diabetes outcomes tend to deteriorate during adolescence (Ashraff et al., 2013; Levine et al., 2001; Mortensen & Hougaard, 1997) has led to a number of interventions being developed with the specific aim of improving adherence to treatment and psychosocial functioning. These have taken a number of approaches including psychoeducation (Murphy et al., 2012), coping skills training (Grey, Boland, Davidson, Li, & Tamborlane, 2000), motivational interviewing (Channon et al., 2007) and family-focussed interventions (Laffel, Vangsness, et al., 2003). These interventions have had varying success, particularly in improving QoL outcomes. There has been little attempt to systematically evaluate ACT or mindfulness approaches for this population. However, similar interventions have been shown to be successful for other paediatric health conditions, including chronic pain (Gauntlett-Gilbert, Connell, Clinch, & McCracken, 2013) and type 2 diabetes (Pivarunas et al., 2015). The current findings suggest acceptance and commitment therapy (ACT) and mindfulness-based approaches may be particularly beneficial for young people with diabetes and their parents.

There are a number of limitations of the current study that must be borne in mind when considering the outcomes. The subject to variable ratio in the regression analysis was smaller than has been recommended by previous simulation studies (e.g. Green, 1991). The danger of a small subject to variable ratio is the possibility the R statistic is artificially inflated through “overfitting” the model. However more recent studies have suggested as little as two subjects per variable is sufficient to obtain a reliable estimation of a linear regression model (Austin & Steyerberg,
2015), which this study achieved. For random data, R can be calculated as $k/(N-1)$, where $k$ is the number of variables and $N$ is the sample size (Field, 2009). In the current study this equates to $R = 0.25$, which is much lower than what has actually been achieved. This increases confidence that the effects found in the current study are not spurious.

The power calculation indicated a sample size of 59 would be required to detect a large effect size with power at the 0.8 level. The sample size fell short of this target. However, post-hoc calculation based on the actual effect sizes of the regression models found that the final models had more than 90% power. This was due to the large effect sizes observed in both models. Despite this, replication in a larger sample size would increase confidence in the findings.

The current sample was also homogenous in terms of both socio-economic status and ethnicity representing a largely white, high SES group. It is not clear then to what extent the results could be generalised to a the wider population. Previous studies investigating the role of parenting in paediatric diabetes outcomes have had demographically comparable samples (e.g. Bartello-Harbaum et al., 2008; Sherifali, Ciliska & O’Mara, 2009) which allows the current results to be compared across similar studies. Future research would however benefit from the recruitment of a more heterogeneous sample to allow the current findings to be confirmed. In addition, the sample consisted of relatively few young people using pumps and it is possible this may have under-represented the outcomes for these young people. However the percentage in this sample (24.4%) is not far from the Scottish national percentage of under 18’s using a pump (28.8%; Scottish Diabetes Survey, 2013). Given the significant role insulin administration played in the study findings it would be beneficial for future studies to have a more balanced sample.
Previous studies have shown (Ciarrochi, Bilich, & Godsell, 2010) specific measures of psychological flexibility tend to be more sensitive. This seems to have been replicated in this study, raising the question of whether a parenting specific measure of psychological flexibility would have been more adequate to test relations with parenting behaviours. Finally, the Parental Bonding Instrument (PBI-BC) did not achieve an alpha co-efficient above 0.7, which is generally regarded as the minimum level for acceptable reliability. It is unclear why this has been the case given it has been shown to be reliable with an adolescent sample in previous studies (Klimidis et al., 1992). Regardless, the findings of the study of relationships between parental care and control should therefore be interpreted with caution.

6. Conclusion

Despite the limitations, the current study represents an important first step in understanding the role of psychological flexibility and mindfulness in adolescents with type 1 diabetes. The results suggest that these constructs are promising for understanding the conditions leading to poor outcomes during this developmental period. However mindfulness and psychological flexibility may play different roles in relation to treatment adherence and QoL. Further research would be beneficial to elucidate these relationship further. A greater understanding could lead to acceptance and mindfulness based interventions that could facilitate improvements in adolescents at risk of poor outcomes.
7. References


among youth with type 1 diabetes. *Pediatric Diabetes*, 9(4 PART 2), 373-381.


Relationship to patient management and diabetes-specific family conflict. *Diabetes Care, 26*(11), 3067-3073.


Thesis References


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adolescents with diabetes mellitus: a systematic review. *Health Technol Assess, 5*(10), 1-79.


with type 1 diabetes mellitus: The KICk-OFF course. *Archives of Disease in Childhood, 93*(11), 927-931.


Appendix A – Journal of Pediatric Psychology Instructions to Authors

Instructions to Authors

The Journal of Pediatric Psychology is an official publication of the Society of Pediatric Psychology, Division 54 of the American Psychological Association. JPP publishes articles related to theory, research, and professional practice in pediatric psychology.

Types of Manuscripts:

- Original research, including case studies
- Review articles
- Commentaries

Manuscript preparation: General Instructions

Full instructions for uploading data and files etc. are given on Manuscript Central at the website under Instructions for online submission:
http://www.oxfordjournals.org/our_journals/jpepsy/for_authors/submission_online.html

Organization of manuscripts

Manuscript Central will guide authors through the submission steps, including: Abstract, Keyword selection, and the Manuscript. The manuscript must contain an Introduction, Methods, Results, Discussion, Acknowledgements and Reference List.

Length of manuscript: Original research articles should not exceed 25 pages, in total, including title page, references, figures, tables, etc. In the case of papers that report on multiple studies or those with methodologies that necessitate detailed explanation, the authors should justify longer manuscript length to the Editor in the cover letter. Case reports should not exceed 20 pages. Review articles should not exceed 30 pages. Commentaries should not exceed 4 pages. The Journal of Pediatric Psychology no longer accepts brief reports but will accept manuscripts that are shorter in length than the 25 page manuscripts.

Manuscripts (text, references, tables, figures, etc.) should be prepared in detailed accord with the Publication Manual of the American Psychological Association (6th ed.). There are two exceptions:

(a) The academic degrees of authors should be placed on the title page following their names, and

(b) a structured abstract of not more than 150 words should be included. The abstract should include the following parts:

(1) Objective (brief statement of the purpose of the study);
(2) Methods (summary of the participants, design, measures, procedure);
(3) Results (the primary findings of this work); and
(4) Conclusions (statement of implications of these data).

Key words should be included, consistent with APA style. Submissions should be double-spaced throughout, with margins of at least 1 inch and font size of 12 points (or 26 lines per page, 12-15 characters per inch). Authors should remove all identifying information from the body of the manuscript so that peer reviewers will be unable to recognize the authors and their affiliations. E-mail addresses, whenever possible, should be included in the author note.

Informed consent and ethical treatment of study participants. Authors should indicate in the Method section of relevant manuscripts how informed consent was obtained and report the approval of the study by the appropriate Institutional Review Board(s). Authors will also be asked to sign a statement, provided by the Editor that they have complied with the American Psychological Association Ethical Principles with regard to the treatment of their sample.
Clinical relevance of the research should be incorporated into the manuscripts. There is no special section on clinical implications, but authors should integrate implications for practice, as appropriate, into papers.

Terminology should be sensitive to the individual who has a disease or disability. The Editors endorse the concept of "people first, not their disability." Terminology should reflect the "person with a disability" (e.g., children with diabetes, persons with HIV infection, families of children with cancer) rather than the condition as an adjective (e.g., diabetic children, HIV patients, cancer families). Nonsexist language should be used.

Special instructions for types of manuscripts

(1) Treatment studies/Randomized controlled trials: If you are submitting a manuscript of a randomized clinical trial to JPP, you are required to submit a flowchart of your research showing the steps found in the Consort E-Flowchart. This should be submitted as a figure. The Consort E-Flowchart and a checklist of items to be included when reporting a randomized trial can both be found on http://www.consort-statement.org Please clearly indicate the page numbers where each checklist item is reported in the manuscript. Please upload this checklist as supplementary material when you submit your manuscript for consideration.

(2) Case Studies: Although there may be some exceptions, most case studies should be sent to Clinical Practice in Pediatric Psychology (CPPP). Single-subject studies that employ rigorous A-B-A-B designs and/or statistical strategies can be sent to JPP. All others will probably fit better with CPPP. Case reports should not exceed 20 pages. Case reports are appropriate to document the efficacy of new treatment applications; to describe new clinical phenomena; to develop hypotheses; to illustrate methodological issues, difficult diagnoses, and novel treatment approaches; and to identify unmet clinical or research needs. Guidelines for case study submissions can be found in Drotar, D. (2009). Editorial: Case Studies and Series: A Call for Action and Invitation for Submissions, Journal of Pediatric Psychology, 34, 795-802; Drotar, D. (2011). Editorial: Guidance for Submitting and Reviewing Case Reports and Series in the Journal of Pediatric Psychology, 36, 951-958.


(4) Review articles: Please consult the recent editorial (New Guidelines for Publishing Review Articles in JPP) which describes new guidelines for review articles, and the Checklist for Preparing and Evaluating Review Articles.

a) Topical reviews: Topical reviews summarize contemporary findings, suggest new conceptual models, or highlight noteworthy or controversial issues in pediatric psychology. They are limited to 2,000 words, contain no more than 2 tables or figures, and have an upper limit of 30 references. Supplementary online material (e.g., additional tables) may be considered on a case by case basis.

b) Systematic reviews: Systematic reviews should not exceed 30 pages. Authors are required to attach the PRISMA checklist and flow diagram as supplementary material for each submission. Authors can find the PRISMA checklist and flow diagram in downloadable templates that can be re-used at this URL, http://www.prisma-statement.org/statement.htm. Authors of systematic reviews that do not include a meta-analysis must provide a clear statement in the manuscript explaining why such an analysis is not included for all or relevant portions of the report.

(5) Commentaries: Commentaries are invited on all topics of interest in pediatric psychology, and should not exceed 4 pages, including references.

(6) Historical Analysis in Pediatric Psychology is a special series of papers devoted to the history of pediatric psychology. Authors interested in submitting a paper for this series should contact the Editor of JPP to discuss potential papers prior to submission. There is no deadline for these papers (they may be submitted anytime). All submissions will be peer reviewed and
should comply fully with the JPP Instructions to Authors. Papers in this series should be tightly focused contributions that expand our understanding of the roots, evolution, and/or impact of pediatric psychology as a discipline. Manuscripts may focus on the influence of individuals, published works, organizations, conceptualizations, philosophies or approaches, or clinical and professional activities. Successful papers should articulate a clear purpose/question and develop a compelling argument for the topic. Contributions should include a breadth of coverage, such that contradictory data are included and potential biases acknowledged. Historical analysis is more than a recounting of the "facts" and should include a thoughtful and scholarly interpretation of the subject matter. Papers should rely on primary sources and must be clearly and appropriately referenced. Supplemental materials to accompany the article may be posted online.

**Additional Guidance:**

The following links provide additional guidance for authors and reviewers. Editorial Policy, Authors’ Checklist, Guidelines for Reviews, Suggestions for Mentored Reviews, "People First," NIH policy, Replication of research, Duplicate and redundant policies Conflict of interest

See the following articles for detailed guidance concerning preparation of manuscripts: Editorial: Thoughts in Improving the Quality of Manuscripts Submitted to the Journal of Pediatric Psychology: How to Write a Convincing Introduction.; Methods: Editorial: How to Report Methods in the Journal of Pediatric Psychology; Results and Discussion: Editorial: How to Write an Effective Results and Discussion Section for the Journal of Pediatric Psychology.

**Funding**

Details of all funding sources for the work in question should be given in a separate section entitled 'Funding'. This should appear before the 'Acknowledgements' section.

The following rules should be followed:
- The sentence should begin: 'This work was supported by …'
- The full official funding agency name should be given, i.e. ‘the National Cancer Institute at the National Institutes of Health’ or simply ‘National Institutes of Health’, not ‘NCI’ (one of the 27 subinstitutions) or ‘NCI at NIH’ (full RIN-approved list of UK funding agencies)
- Grant numbers should be complete and accurate and provided in parentheses as follows: '(grant number xxxx)'
- Multiple grant numbers should be separated by a comma as follows: '(grant numbers xxxx, yyyy)'
- Agencies should be separated by a semi-colon (plus ‘and’ before the last funding agency)
- Where individuals need to be specified for certain sources of funding the following text should be added after the relevant agency or grant number ‘to [author initials].

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offer similar services and you can also use any of these. Authors are liable for all costs associated with such services.

Updated January 2016
Appendix B – Journal of Contextual Behavioral Science Instructions to Authors

Use of word processing software
It is important that the file be saved in the native format of the word processor used. The text should be in single-column format. Keep the layout of the text as simple as possible. Most formatting codes will be removed and replaced on processing the article. In particular, do not use the word processor’s options to justify text or to hyphenate words. However, do use bold face, italics, subscripts, superscripts etc. When preparing tables, if you are using a table grid, use only one grid for each individual table and not a grid for each row. If no grid is used, use tabs, not spaces, to align columns. The electronic text should be prepared in a way very similar to that of conventional manuscripts (see also the Guide to Publishing with Elsevier). Note that source files of figures, tables and text graphics will be required whether or not you embed your figures in the text. See also the section on Electronic artwork.
To avoid unnecessary errors you are strongly advised to use the ‘spell-check’ and ‘grammar-check’ functions of your word processor.

Article structure

Subdivision - unnumbered sections
Divide your article into clearly defined sections. Each subsection is given a brief heading. Each heading should appear on its own separate line. Subsections should be used as much as possible when cross-referencing text: refer to the subsection by heading as opposed to simply 'the text'.

Introduction
State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

Material and methods
Provide sufficient detail to allow the work to be reproduced. Methods already published should be indicated by a reference: only relevant modifications should be described.

Theory/calculation
A Theory section should extend, not repeat, the background to the article already dealt with in the Introduction and lay the foundation for further work. In contrast, a Calculation section represents a practical development from a theoretical basis.

Results
Results should be clear and concise.

Discussion
This should explore the significance of the results of the work, not repeat them. A combined Results and Discussion section is often appropriate. Avoid extensive citations and discussion of published literature.

Conclusions
The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

Appendices
If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

Essential title page information
• Title. Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.
• Author names and affiliations. Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. Present the authors’ affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author’s name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.
• Corresponding author. Clearly indicate who will handle correspondence at all stages of
refereeing and publication, also post-publication. **Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.**

- **Present/permanent address.** If an author has moved since the work described in the article was done, or was visiting at the time, a ‘Present address’ (or ‘Permanent address’) may be indicated as a footnote to that author’s name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

**Abstract**

A concise and factual abstract is required. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, References should be avoided, but if essential, then cite the author(s) and year(s). Also, non-standard or uncommon abbreviations should be avoided, but if essential they must be defined at their first mention in the abstract itself.

**Graphical abstract**

Although a graphical abstract is optional, its use is encouraged as it draws more attention to the online article. The graphical abstract should summarize the contents of the article in a concise, pictorial form designed to capture the attention of a wide readership. Graphical abstracts should be submitted as a separate file in the online submission system. Image size: Please provide an image with a minimum of 531 × 1328 pixels (h × w) or proportionally more. The image should be readable at a size of 5 × 13 cm using a regular screen resolution of 96 dpi. Preferred file types: TIFF, EPS, PDF or MS Office files. You can view Example Graphical Abstracts on our information site.

Authors can make use of Elsevier’s Illustration and Enhancement service to ensure the best presentation of their images and in accordance with all technical requirements: Illustration Service.

**Highlights**

Highlights are mandatory for this journal. They consist of a short collection of bullet points that convey the core findings of the article and should be submitted in a separate editable file in the online submission system. Please use ‘Highlights’ in the file name and include 3 to 5 bullet points (maximum 85 characters, including spaces, per bullet point). You can view example Highlights on our information site.

**Keywords**

Immediately after the abstract, provide a maximum of 6 keywords, using American spelling and avoiding general and plural terms and multiple concepts (avoid, for example, ‘and’, ‘of’). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

**Abbreviations**

Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in the footnote. Ensure consistency of abbreviations throughout the article.

**Acknowledgements**

Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

**Formatting of funding sources**

List funding sources in this standard way to facilitate compliance to funder’s requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions on the program or type of grants and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

If no funding has been provided for the research, please include the following sentence: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.
Math formulae
Please submit math equations as editable text and not as images. Present simple formulae in line with normal text where possible and use the solidus (/) instead of a horizontal line for small fractional terms, e.g., X/Y. In principle, variables are to be presented in italics. Powers of e are often more conveniently denoted by exp. Number consecutively any equations that have to be displayed separately from the text (if referred to explicitly in the text).

Footnotes
Footnotes should be used sparingly. Number them consecutively throughout the article. Many word processors can build footnotes into the text, and this feature may be used. Otherwise, please indicate the position of footnotes in the text and list the footnotes themselves separately at the end of the article. Do not include footnotes in the Reference list.

Artwork
Electronic artwork
General points
• Make sure you use uniform lettering and sizing of your original artwork.
• Embed the used fonts if the application provides that option.
• Aim to use the following fonts in your illustrations: Arial, Courier, Times New Roman, Symbol, or use fonts that look similar.
• Number the illustrations according to their sequence in the text.
• Use a logical naming convention for your artwork files.
• Provide captions to illustrations separately.
• Size the illustrations close to the desired dimensions of the published version.
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A detailed guide on electronic artwork is available.

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Formats
If your electronic artwork is created in a Microsoft Office application (Word, PowerPoint, Excel) then please supply 'as is' in the native document format. Regardless of the application used other than Microsoft Office, when your electronic artwork is finalized, please 'Save as' or convert the images to one of the following formats (note the resolution requirements for line drawings, halftones, and line/halftone combinations given below):
EPS (or PDF): Vector drawings, embed all used fonts.
TIFF (or JPEG): Color or grayscale photographs (halftones), keep to a minimum of 300 dpi.
TIFF (or JPEG): Bitmapped (pure black & white pixels) line drawings, keep to a minimum of 1000 dpi.
TIFF (or JPEG): Combinations bitmapped line/half-tone (color or grayscale), keep to a minimum of 500 dpi.

Please do not:
• Supply files that are optimized for screen use (e.g., GIF, BMP, PICT, WPG); these typically have a low number of pixels and limited set of colors;
• Supply files that are too low in resolution;
• Submit graphics that are disproportionately large for the content.

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Please make sure that artwork files are in an acceptable format (TIFF (or JPEG), EPS (or PDF), or MS Office files) and with the correct resolution. If, together with your accepted article, you submit usable color figures then Elsevier will ensure, at no additional charge, that these figures will appear in color online (e.g., ScienceDirect and other sites) regardless of whether or not these illustrations are reproduced in color in the printed version. For color reproduction in print, you will receive information regarding the costs from Elsevier after receipt of your accepted article. Please indicate your preference for color: in print or online only. Further information on the preparation of electronic artwork.

Figure captions
Ensure that each illustration has a caption. Supply captions separately, not attached to the figure. A caption should comprise a brief title (not on the figure itself) and a description of the illustration. Keep text in the illustrations themselves to a minimum but explain all symbols and abbreviations used.

Tables
Please submit tables as editable text and not as images. Tables can be placed either next to
the relevant text in the article, or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules.

References

Citation in text
Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either 'Unpublished results' or 'Personal communication'. Citation of a reference as 'in press' implies that the item has been accepted for publication.

Web references
As a minimum, the full URL should be given and the date when the reference was last accessed. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list.

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Reference style

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List: references should be arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year must be identified by the letters 'a', 'b', 'c', etc., placed after the year of publication.

Examples:
Reference to a journal publication:
Reference to a book:
Reference to a chapter in an edited book:
Reference to a website:
http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/ Accessed 13.03.03.

Video data

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Supplementary material

Supplementary material can support and enhance your scientific research. Supplementary files offer the author additional possibilities to publish supporting applications, high-resolution images, background datasets, sound clips and more. Please note that such items are published online exactly as they are submitted; there is no typesetting involved (supplementary data supplied as an Excel file or as a PowerPoint slide will appear as such online). Please submit the material together with the article and supply a concise and descriptive caption for each file. If you wish to make any changes to supplementary data during any stage of the process, then please make sure to provide an updated file, and do not annotate any corrections on a previous version. Please also make sure to switch off the 'Track Changes' option in any Microsoft Office files as these will appear in the published supplementary file(s). For more detailed instructions please visit our artwork instruction pages.

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The journal encourages authors to create an AudioSlides presentation with their published article. AudioSlides are brief, webinar-style presentations that are shown next to the online article on ScienceDirect. This gives authors the opportunity to summarize their research in their own words and to help readers understand what the paper is about. More information and examples are available. Authors of this journal will automatically receive an invitation e-mail to create an AudioSlides presentation after acceptance of their paper.

Submission checklist

The following list will be useful during the final checking of an article prior to sending it to the journal for review. Please consult this Guide for Authors for further details of any item. **Ensure that the following items are present:**

One author has been designated as the corresponding author with contact details:

- E-mail address
- Full postal address

All necessary files have been uploaded, and contain:

- Keywords
- All figure captions
- All tables (including title, description, footnotes)

Further considerations:

- Manuscript has been 'spell-checked' and 'grammar-checked'
- References are in the correct format for this journal
- All references mentioned in the Reference list are cited in the text, and vice versa
- Permission has been obtained for use of copyrighted material from other sources (including the Internet)

Printed version of figures (if applicable) in color or black-and-white

- Indicate clearly whether or not color or black-and-white in print is required.

For any further information please visit our Support Center.
## Appendix C – Quality Criteria Tool

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Was there a control group?</th>
<th>Present: More than 1 group are assessed at baseline and post-treatment. Could be active or non-active control. Absent: Only 1 group is assessed (i.e. before/after study only).</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Was allocation to groups randomised?</td>
<td>Present: Clear information is given on method of randomisation and is suitable for study design (e.g. random number generation) Absent: Randomisation did not occur or is not adequately detailed.</td>
</tr>
<tr>
<td>1.2</td>
<td>Was allocation to groups concealed?</td>
<td>Present: Adequate measures taken to conceal allocation to group at entry to study and post-treatment for those completing assessed measures. Absent: No attempt to conceal group allocation or concealment not possible.</td>
</tr>
<tr>
<td>1.3</td>
<td>Was there an adequate length of follow up after participation in intervention?</td>
<td>Present: Follow up assessment occurred at least 6 months after commencement of the intervention. Absent: No follow up assessment was undertaken or occurred less than 6 months after commencement of the intervention.</td>
</tr>
<tr>
<td>1.4</td>
<td>Was the sample size sufficient?</td>
<td>Present: A power calculation has been provided and demonstrates adequate power at 0.8 level with p&lt;0.05 or must have at least 51 subjects per group for between group differences. Absent: No power calculation provided and did not achieve at least 51 subjects per group. Power calculation provided but does not reach 0.8 level.</td>
</tr>
<tr>
<td></td>
<td>Sample</td>
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<td>---</td>
<td>-------------------------------------------------------------------------------------------</td>
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<tr>
<td>2.1</td>
<td>Was the sample representative of the population?</td>
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<tr>
<td></td>
<td>Present: Probability sampling methods used to minimise risk of bias in recruitment.</td>
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<tr>
<td></td>
<td>Inclusion/exclusion criteria not unduly rigorous and applied the same to all groups.</td>
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<tr>
<td></td>
<td>Similar participation rates between groups.</td>
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<tr>
<td></td>
<td>Absent: Sampling method likely to introduce bias through being highly selected for example</td>
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<tr>
<td></td>
<td>only volunteers or few of those invited eventually participated. Large difference in</td>
<td></td>
</tr>
<tr>
<td></td>
<td>participation rates between groups.</td>
<td></td>
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<tr>
<td>2.2</td>
<td>Were confounding factors sufficiently controlled for?</td>
<td></td>
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<tr>
<td></td>
<td>Present: Possible confounding factors are measured at baseline and are adequately</td>
<td></td>
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<tr>
<td></td>
<td>controlled for either in analysis or through a matched control group. Participants in</td>
<td></td>
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<tr>
<td></td>
<td>each group are assessed and compared at baseline for key variables which may impact</td>
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</tr>
<tr>
<td></td>
<td>intervention outcomes (e.g. QoL, HbA1C, age).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Absent: No attempt to identify confounding factors or no control for these either through</td>
<td></td>
</tr>
<tr>
<td></td>
<td>matched group or in analysis.</td>
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<tr>
<td>2.3</td>
<td>Are attrition rates clearly stated and, where applicable, are attrition rates similar</td>
<td></td>
</tr>
<tr>
<td></td>
<td>between groups?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Present: Attrition rates are clearly stated and are no greater than 30%. Where</td>
<td></td>
</tr>
<tr>
<td></td>
<td>applicable, attrition rates of all groups are clearly stated and there is no greater</td>
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<tr>
<td></td>
<td>than 20% difference between groups.</td>
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<tr>
<td></td>
<td>Absent: Attrition rates are not clearly stated for all groups. Attrition rates between</td>
<td></td>
</tr>
<tr>
<td></td>
<td>groups are greater than 20% and/or greater than 30% overall for either group.</td>
<td></td>
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</tbody>
</table>
| Intervention | 3.1 | Is intervention clearly defined and operationalised? | **Present**: A clearly defined treatment protocol has been established and is accessible or enough information has been provided to allow the intervention to be replicated.  
**Absent**: Intervention is not clearly described and/or there is no accessible protocol. |
| --- | --- | --- | --- |
| | 3.2 | Was fidelity checked? | **Present**: There has been some attempt to ensure fidelity through measures such as a manualised protocol, trained facilitators, facilitator supervision, and videotaped intervention sessions.  
**Absent**: No apparent attempts to ensure fidelity. |
| Outcomes | 4.1 | Were outcomes measured using standard, valid and reliable tools? | **Present**: Standard outcome measures of key variables used with well reported psychometric properties (i.e. validity and reliability) in a paediatric diabetes population. Key variables assessed pre and post intervention.  
**Absent**: Outcome measure inappropriate for variable being measured and/or has poor psychometric properties. Key variables measures at one time point only. |
| Analysis | 5.1 | Was the statistical analysis appropriate for the study design and data collected? | **Present**: The statistical analysis used is appropriate for the study design and takes account of the type of data collected.  
**Absent**: Statistical analysis used is inappropriate for the study design and/or data. |
| | 5.2 | Was an Intention to Treat analysis carried out? | **Present**: An appropriate ITT analysis has been undertaken (e.g. carrying forward last known score) to minimise bias.  
**Absent**: No attempt made to made to deal with lost data due to attrition and/or other reasons. |
<table>
<thead>
<tr>
<th>Overall Quality</th>
<th>Quality</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>+++</td>
<td>High Quality</td>
<td>Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research.</td>
</tr>
<tr>
<td>++</td>
<td>Acceptable</td>
<td>Most criteria met. Some flaws in the study with an associated risk of bias. Conclusions may change in the light of further studies.</td>
</tr>
<tr>
<td>+</td>
<td>Low Quality</td>
<td>Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.</td>
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### Appendix D – Excluded Studies

#### Table A.2 Excluded studies and reasons for exclusion

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<td></td>
<td>(Hernandez, 2004)</td>
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<tr>
<td></td>
<td>(Shaban &amp; Jones, 2013)</td>
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<tr>
<td></td>
<td>(Watkinson, 2001)</td>
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<tr>
<td></td>
<td>(Weinger, 1999)</td>
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<tr>
<td></td>
<td>(Scott, 2012)</td>
</tr>
<tr>
<td>Out of age range / adult population</td>
<td>(Hernandez &amp; Williamson, 2004)</td>
</tr>
<tr>
<td></td>
<td>(Cooke et al., 2013)</td>
</tr>
<tr>
<td></td>
<td>(Grey et al., 1998)</td>
</tr>
<tr>
<td></td>
<td>(Grey, Boland, Davidson, Yu, &amp; Tamborlane, 1999)</td>
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<td>(Grey, Boland, Davidson, Li, &amp; Tamborlane, 2000)</td>
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<tr>
<td></td>
<td>(Halbron et al., 2014)</td>
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<td></td>
<td>(Hanestad &amp; Albrektsen, 1993)</td>
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<tr>
<td></td>
<td>(Muller, Kloos, Samann, Wolf, &amp; Muller, 2013)</td>
</tr>
<tr>
<td></td>
<td>(Weinger et al., 2011)</td>
</tr>
<tr>
<td></td>
<td>(van der Ven et al., 2005)</td>
</tr>
<tr>
<td></td>
<td>(Abolfotouh, Kamal, El-Bourgy, &amp; Mohamed, 2011)</td>
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<tr>
<td>Intervention medical/case management/not psychologically informed</td>
<td>(Boogerd, Noordam, Kremer, Prins, &amp; Verhaak, 2014)</td>
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<td></td>
<td>(Engelke, Guttu, Warren, &amp; Swanson, 2008)</td>
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<tr>
<td></td>
<td>(Han et al., 2015)</td>
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<tr>
<td></td>
<td>(Hanberger, Ludvigsson, &amp; Nordfeldt, 2013)</td>
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<td>Studies</td>
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<td>-----------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
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<td>(Grey, Jaser, Whittemore, Jeon, &amp; Lindemann, 2011)</td>
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<td>(Monaghan, Hilliard, Cogen, &amp; Streisand, 2011)</td>
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<td>(De Wit et al., 2008)</td>
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<td></td>
<td>(de Wit et al., 2010)</td>
</tr>
<tr>
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<td></td>
<td>(Lange, Sassmann, von Schutz, Kordonouri, &amp; Danne, 2007)</td>
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<td>(Sawtell et al., 2015)</td>
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<td></td>
<td>(Noyes et al., 2010)</td>
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<tr>
<td>Article not available in English/ Full text not accessible</td>
<td>(Haisch, Lang-Hatzfeld, Bruckel, &amp; Bohm, 1996)</td>
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<td>(Løding &amp; Wold, 2006)</td>
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<td>(Weyhreter, Holl, Beerstecher, &amp; Borsch, 2008)</td>
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<td>(Matam, Kumaraiah, Munichoodappa, Kumar, &amp; Aravind, 2000)</td>
</tr>
<tr>
<td></td>
<td>(Schiel, Kaps, Weihs-Godenrath, &amp; Kostin, 2012)</td>
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</tbody>
</table>
Appendix E – Information Sheets

DOCTORATE IN CLINICAL PSYCHOLOGY

YOUNG PERSON’S INFORMATION SHEET

A study to understand the relationships between psychological flexibility, mindfulness, perception of parental control and diabetes-related outcomes.

Researcher – Lorraine Lockhart
Telephone number – 01324 614349

Supervisor – Dr Nuno Ferreira
Telephone Number – 0131 651 3972

You have been invited to take part in a research study. Before you decide if you want to take part, it is important for you to know what the study is and what it will involve. This information sheet will help you decide if you want to take part or not. If there is anything you are not sure about you can talk it over with your parents or diabetes nurse.

Why is this study being carried out?

We are interested in the ways people react to their thoughts and feelings, especially thoughts and feelings about diabetes and how protective their parents are. We are also interested in how this might impact on young people’s experience of life with diabetes and how much they follow their treatment plan.

Why have you been invited?
Young people aged between 12 – 18 years old who have been diagnosed with type 1 diabetes for over a year are being asked to take part along with their parent. You have been asked because you are within this age range and you attend regular outpatient appointments for type 1 diabetes.

Do you have to take part?
No. You can decide whether or not you want to take part. Even if your parent thinks you should take part you still get to make the final decision. You should only take part if you want to. You will be given this information sheet to keep so you can read over it in your own time. Even if your parent does not want to complete the questionnaire you can still take part if you want to.

If you do decide to take part, you can change your mind at any time and you don’t have tell anyone why you have changed your mind.
Nothing will change about your clinic appointments whether you take part or not.

**What will happen if you decide to take part?**

You will meet with the researcher, Lorraine Lockhart at one of your clinic appointments in about 3 months time. You can ask any questions before you agree to take part. If you decide to take part you will be asked to sign a consent form to say that you have read this information sheet, you know what is involved in the study and that you are happy to participate.

You will then be asked to fill out a questionnaire. The questionnaire will ask about how you react to your thoughts and feelings, particularly thoughts and feelings about your diabetes and how protective your parents are. It will also ask you about how much you stick to your treatment plan and how your diabetes treatment impacts on your life.

It normally takes about 25 minutes to answer all the questions. We will ask one of your parents to fill out a questionnaire too.

**What are the benefits of taking part?**

You might not benefit directly from taking part in the research. Hopefully the research will help other young people with diabetes in the future. The answers you and other young people give to the questionnaires will help us to better understand the kinds of things that help all young people to manage their diabetes the best they can. We hope we can use this information to help other young people with diabetes in the future.

**What are the disadvantages and risks of taking part in the research?**

The questionnaires you will be asked to complete will ask about the way you react to thoughts and feelings, how you manage your diabetes treatment, the effect diabetes has on your life and how protective you think your parents are. If any of these subjects are things you worry about already it might be that answering the questions might make you upset or uncomfortable.

If you do get upset or uncomfortable you can stop at any time. You can also talk to your diabetes nurse about anything that you find upsetting in the questionnaires.

**Who has decided the study can go ahead?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This study was looked at by the West of Scotland Research Ethics Committee and they have agreed the study can go ahead. The study has also been checked by Dr Nuno Ferreira, a lecturer at the University of Edinburgh. Managers within the NHS have also agreed the study can go ahead.
What will happen to the information that you give?

The researcher will collect everyone’s answers to the questionnaires and will put the information into a database. **No one looking at the information would be able to know that you have taken part.**

The researcher will write a report about the study. **No one will know from reading the report that you have taken part.** Even after you have finished the questionnaires you can ask the researcher to take all your information off the database.

We keep the answers to your questionnaires for 10 years in case the information given in any reports have to be checked. Sometimes we let other researchers use the information for other projects. **No one will know from looking at the information that you have taken part.**

To make sure that the study is being run correctly, we will ask your permission for responsible representatives from the Sponsor and NHS Institution to access information collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

What to do now?

You can talk over this information sheet with your parents or your diabetes nurse before you decide if you want to take part.

If you have any further questions about the study you can contact the researcher or ask your parents to do this for you by calling Lorraine Lockhart on: 01324 614349 or email: lorrainelockhart@nhs.net

If you would like to talk to someone who is not part of the research team please contact Dr Jill Cossar on 0131 651 3972.

If you wish to make a complaint about the study please contact NHS Lothian:

NHS Lothian Complaints Team
2nd Floor
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5708

Email: craft@nhslothian.scot.nhs.uk

**Thank you for taking time to read this information.**
You and your child are being invited to take part in a research study. Before you decide if you are happy to take part, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why is this study being carried out?
This study is being carried out to better understand the ways in which young people react to their thoughts and feelings, particularly their thoughts and feelings about diabetes and how protective their parents are. We are also interested in how parents’ reaction to their thoughts and feelings might influence how a young person reacts to their own. Finally we are interested in how this might influence how young people experience their life with diabetes and how it impacts on how they manage their diabetes.

The researcher is employed as a Trainee Clinical Psychologist by NHS Forth Valley and is studying on the Doctorate in Clinical Psychology at the University of Edinburgh. As part of this course she has to carry out a research project. This study is part of that project.

Why have you been invited?
We are particularly interested in the experience of young people aged 12-18 years old who have been diagnosed with type 1 diabetes for more than a year and their parents. We are asking young people who fit this description throughout Scotland to take part. You are being asked to take part because your child fits this description and we are interested in both their experience and your own.

Do you have to take part?
No. You can decide whether or not you will take part. Your child will also have to agree to take part too. You will be given this information sheet to keep and you will be asked to sign a consent form to agree that you are happy to participate. If you do decide to take part, you are still free to leave the study at any time without giving a reason. Your child can also
withdraw their consent at any time. A decision to leave at any time, or a decision not to take part, will not affect the support you and your family receive from your diabetes team.

What will happen if you decide to take part?
The researcher will meet with you at your child’s next diabetes clinic appointment in approximately 3 months. You will have the opportunity to ask questions before you make a final decision to take part. If you decide to take part the researcher will ask you to sign a consent form to say that you have been given this information sheet, you understand what is involved in the study and you are happy to participate. We will also ask your child to sign a consent form.

You and your child will then be asked to complete a questionnaire each. The questionnaire you are being asked to complete asks about how you react to your thoughts and feelings. It will also ask you about some demographic information. The questionnaire normally takes about 20 minutes to complete.

Your child will also be asked to complete a questionnaire. As well as asking about how they react to their thoughts and feelings, the young person’s questionnaire also asks about how protective they think you are as a parent and how they experience their life with diabetes. The questionnaire normally takes young people around 25 minutes to complete.

If you find any of the questions upsetting or you think your child is upset about the issues raised in the questionnaires you can talk this over with your diabetes nurse.

What will happen to the information that you give?
The answers you and your child give to the questionnaires will be collected by the researcher and entered onto a database. There will be no information collected that would allow anyone to identify you. We will analyse this information and the results of the analysis will be complied into a report. No one will know from reading the report that you have participated. If you take part in the study and you or your child later decide you no longer want to participate then you can ask for your information to be taken off the database and all information destroyed. This will not affect the service you receive from your diabetes team.

When the project is complete the information gathered will be archived for 10 years. We keep this information in case it needs to be checked to be verified at any time. We sometimes allow other researchers to use the information collected if they are carrying out a similar project. However, no one looking at the information would know that you or your child have participated.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor and NHS Institution to access data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity

Will you benefit directly from this research study?
Although taking part in the study might not help you or your child directly, we hope that it will help us to better understand what factors can contribute to creating a better experience for young people living with diabetes. This means we can develop effective
intervention packages that can improve health outcomes for all young people who live with diabetes.

What are the possible disadvantages and risks of taking part?
The questionnaires you and your child will be asked to complete will ask you about how you react to thoughts and feelings. Your child will also be asked to complete questionnaires about their diabetes treatment and how protective they think you are as a parent. As these can sometimes be sensitive subjects some people may find them upsetting. However the questionnaires do not ask you for personal information in relation to these subjects – only to state how much you agree with given statements.

If you or your child become upset or uncomfortable while completing the questionnaires you can stop at any time. You can also speak to one of your diabetes healthcare professional if any if the topics covered are causing you problems.

Who has reviewed the study?
The study proposal has been reviewed by Dr Nuno Ferreira, University of Edinburgh. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from West of Scotland REC. NHS management approval has also been obtained.

What to do now?
You should take some time to discuss the study with your child. You could also discuss taking part in the study with a member of your diabetes team (for example, your diabetes nurse). The researcher will also be available at the clinic to answer questions before you agree to take part.

If you have any further questions about the study please contact Lorraine Lockhart on: 01324 614349 or email: lorrainelockhart@nhs.net

If you would like to discuss this study with someone independent of the study team please contact Dr Jill Cossar on 0131 651 3972.

If you wish to make a complaint about the study please contact NHS Lothian:

NHS Lothian Complaints Team
2nd Floor
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5708

Email: craft@nhslothian.scot.nhs.uk

Thank you for taking time to read this information.
Appendix F – Consent Forms

Version 1 07.12.14 Mindfulness, Psychological Flexibility, Parenting and T1D Outcomes

PARTICIPANT CONSENT FORM

A study to understand the relationships between psychological flexibility, mindfulness, perception of parental control and diabetes-related outcomes.

Researcher – Lorraine Lockhart
Telephone number – 01324 614349

Supervisor – Dr Nuno Ferreira
Telephone Number – 0131 651 3972

1. I agree that I have read and understand the information sheet I have been given (version 1 dated 07.12.14). I have had the chance to think about this, ask questions and have had these answered. □

2. I understand that taking part in the study is voluntary and only I can decide whether or not to take part. I know I can change my mind at any time without giving a reason. □

3. I understand that I will be asked to complete a questionnaire. □

4. I agree my anonymous information can be used for future ethically approved research projects. □

5. I understand that relevant sections of data collected during the study may be looked at by individuals from the regulatory authorities and from the Sponsors NHS Lothian and the University of Edinburgh or from other NHS Board(s) where it is relevant to my taking part in this research. I give permission for those individuals to have access to my data. □

6. I agree to take part in the above study. □

______________________________  ___________________________  ________________________
Name of Participant                  Date                          Signature

______________________________  ___________________________  ________________________
Name of Person taking consent        Date                          Signature

Page 1 of 1  Original (x1) to be retained by researcher. Copy (x1) to be retained by the participant.
PARENT CONSENT FORM

A study to understand the relationships between psychological flexibility, mindfulness, perception of parental control and diabetes-related outcomes.

Researcher – Lorraine Lockhart
Telephone number – 01324 614349

Supervisor – Dr Nuno Ferreira
Telephone Number – 0131 651 3972

1. I confirm that I have read and understand the information sheet for the above study (version 1 dated 07.12.14). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without our medical care or legal rights being affected.

3. I understand that I will be asked to complete a questionnaire.

4. I give permission for our anonymous information to be used for future ethically approved research projects.

5. I understand that relevant sections of data collected during the study may be looked at by individuals from the regulatory authorities and from the Sponsors NHS Lothian and the University of Edinburgh or from other NHS Board(s) where it is relevant to my taking part in this research. I give permission for those individuals to have access to my data.

6. I agree to take part in the above study.

---

Please initial

Name of Participant __________________________ Date _____________ Signature __________________________

Name of Person taking consent __________________________ Date _____________ Signature __________________________

Page 1 of 1 Original (x1) to be retained by researcher. Copy (x1) to be retained by the participant.
Appendix G - Ethical Opinion

Office for Research Ethics Committees
Northern Ireland (ORECNI)
Customer Care & Performance Directorate
Office Suite 3
Lisburn Square House
Haslem’s Lane
Lisburn
Co. Antrim BT28 1TW
Tel: +44 (0) 28 9260 3107
Fax: +44 (0) 28 9260 3619
www.orecni.hscni.net

HSC REC B
28 March 2015

Mrs Lorraine Lockhart
9 Second Street
Birkenshaw
Uddingston
G71 6AT

Dear Mrs Lockhart

Study title: The relationship between mindfulness, psychological flexibility, perceived parental control and diabetes-related outcomes in adolescents with type 1 diabetes.

REC reference: 15/NI/0052
IRAS project ID: 167003

Thank you for your letter of 20 March 2015, responding to the Proportionate Review Sub-Committee’s request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, receb@hscni.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion
The favourable opinion is subject to the following conditions being met prior to the start of the study.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to

Providing Support to Health and Social Care
facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.r dorum.nhs.uk.

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials
All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportun e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites
The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents
The documents reviewed and approved by the Committee are:

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Statement of compliance
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review
Reporting requirements
The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback
You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: [http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance](http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance)

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training
days – see details at http://www.hra.nhs.uk/hra-training/

15/N/0052 Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project.

Yours sincerely

[Signature]

Dr Sarah Anne Moorhead
Chair

Email: recb@hscni.net

Enclosures: “After ethical review – guidance for researchers” [SL-AR2]

Copy to: Prof Jo-Anne Robertson

Ms Susan Shepherd, NHS Lothian
Appendix H – Test of Assumption of Regression Analyses

Multi-collinearity

Multicollinearity was assessed using the Variance Inflation Factor (VIF). In both analyses the VIF for all predictor variables were below 10 and therefore within acceptable limits. In addition, the average VIF was 1.21 in the adherence to treatment analysis and 1.13 in the QoL analysis, both of which are very close to 1 indicating reduced risk of bias in the regression. A tolerance level below 0.2 indicates a potential problem. No variables in either analysis had a tolerance level below 0.2.

Casewise Diagnostics

In an ordinary sample it would be expected that 95% of cases would have standardised residuals +/- 2. In the adherence to treatment analysis, 3 cases were identified outside this limit, representing 6.7% of the sample and therefore close to the 5% specified. In the QoL analysis 1 case was identified outside this limit, representing 2% of the sample and therefore within expected limits. 99% of cases should lie within +/- 2.5. For both analyses all cases were within this limit and therefore it can be safe to assume none of these cases were unduly influencing the regression models.

Using diagnostic statistics, all Cook’s distance values were below 1, indicating no case was unduly influencing the models. The average leverage in the models can be calculated as \( (k + 1/n) = 0.27 \) in both. None of the cases exceeded twice this average \( (i.e. \ 0.54) \) and therefore it could be concluded that no case is unduly influencing the models. All standardised DF Beta statistics fell within the range of +/-1.
Independence of Errors

The assumption of independence of errors was assessed using the Durbin-Watson test. As a rule of thumb values smaller than 1 and larger than 3 suggests correlation of errors. The closer to 2 the better. The value for the adherence to treatment model was 1.606. Critical values suggest a value between 0.927 and 1.834 should be considered inconclusive. However the actual value (i.e. 1.606) is close to the upper limit. The value for the QoL model was 2.507. Critical values suggest a value between 0.927 and 1.834 should be considered inconclusive. The value is therefore lower than 3 but not within the inconclusive range and can be considered acceptable.

Heteroscedasticity and Linearity

Examination of the p-plots of standardised residuals and standardised predicted values show no sign of heteroscedasticity and did not violate assumption of linearity in either analysis (Figures I.1 and I.2).
Figure I.1 scatterplot of standardised residuals and standardised predicted values for treatment adherence analysis.

Figure I.2 scatterplot of standardised residuals and standardised predicted values for QoL analysis.
Normally Distributed Errors

Exploration of histograms of the standardised residuals of the regression models showed relatively normal distributions however there was some skew in the residuals in the QoL model (Figures I.3 and I.4.)

Figure I.3. Histogram of standardised residuals for treatment adherence model.

Figure I.4. Histogram of standardised residuals for QoL model.
The normal probability plots for both models showed some values falling far from the line suggesting the possibility of a non-normal distribution of errors (Figures I.5 and I.6). However in both analyses, a Kolmogorov-Smirnov test of the standardised residuals was non-significant (p>0.05) and therefore it is likely the residuals were normally distributed in both models.

Figure I.5. Normal P-plot of standardised residuals in treatment adherence model.

Figure I.6. Normal P-plot of standardised residuals in QoL model.
Appendix I. Thesis Lay Summary

The lay summary is a brief summary intended to facilitate knowledge transfer and enhance accessibility, therefore the language used should be non-technical and suitable for a general audience. (See the Degree Regulations and Programmes of Study, General Postgraduate Degree Programme Regulations. These regulations are available via: http://www.drps.ed.ac.uk/.)

<table>
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This thesis aimed to contribute to our understanding of how to improve health outcomes for young people with type 1 diabetes. Treatment for diabetes can be complex. It requires daily monitoring of blood glucose levels, food intake and exercise, as well as multiple daily insulin injections. Treatment can interfere with everyday life and can cause increased stress for young people and families. However the consequences of poor diabetes management can be serious and life-threatening.

Adolescence seems to be a particularly difficult time for young people. For some young people sticking to their treatment is challenging. Parent involvement in treatment can be of benefit. However this only seems to be the case when parents are seen by their children to be warm and caring. The challenge for clinicians is to understand how they can effectively help young people and families to successfully manage the medical and psychological aspects of the condition.

This thesis contributed to this in two ways; by identifying what is already known about how to improve outcomes for young people with type 1 diabetes and exploring potential areas that could be targeted to improve outcomes.

The initial part of the thesis describes a review of the existing literature that was undertaken. A number of academic databases were searched to identify original research studies looking at interventions for children and young people with type 1 diabetes. This review was particularly interested in interventions to improve health-related quality of life. Health related quality of life refers to a person’s beliefs about how much their...
health and healthcare impact on their life. This provides a picture of a person’s physical, social and psychological well-being.

The database search identified 22 original research studies that measured health related quality of life at the start and at the end of the intervention. The review concluded that many of the interventions had a primary aim of improving physical outcomes. Few were designed to improve quality of life. Despite this, eight of the studies reported improvements in health related quality of life for young people participating in the interventions. There was evidence to suggest training in coping skills and intensive, structured education can be effective.

The latter part of the thesis describes an original research study. The study explored how health outcomes for adolescents are impacted by the way young people and parents react to their thoughts and feelings. Psychological flexibility refers to a person’s ability to experience what is going on inside them, such as thoughts, feelings and sensations, without needing to react to them or get rid of them. This allows for a person to act in a way that matches their values and goals, even when this is difficult. Psychological flexibility requires a person to be mindful. Mindfulness refers to a person’s ability to fully experience what is going on at the present moment with a non-judgmental attitude.

The study explored whether health outcomes for young people are associated with how psychologically flexible or mindful they are. It also explored if there is an association between how psychologically flexible or mindful a parent is and whether their child sees them as caring or controlling. Forty five parents and adolescents under the care of paediatric diabetes teams agreed to participate. They completed a number of questionnaires.

The study found that adolescents were more likely to stick to their treatment when they, and their parents, were more psychologically flexible. In addition, adolescents reported better quality of life when they also reported being more mindful. Young people who used an insulin pump instead of insulin injections also reported having worse quality of life.

Overall, the thesis suggests that psychologically informed interventions can be of benefit to young people with type 1 diabetes. In addition, interventions which aim to increase mindfulness and psychological flexibility, such as Acceptance and Commitment Therapy, may also be prove to be useful.