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SSR  Essay Question Paper  Thesis

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Do attachment security, self-esteem and emotional distress predict metabolic control and quality of life in adolescents with Type 1 diabetes? Will ‘wellbeing’ text-messaging support improve outcomes?

Mary Swan

Doctorate in Clinical Psychology
University of Edinburgh
August 2012
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Overall word count (including references) 31777

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(Referencing style as per Pediatric Diabetes Author Guidelines, appendix 11)
Declaration of own work
Acknowledgements

I would like to thank my clinical supervisor Dr Vicki Dunbar for her support and encouragement, knowledge and expertise throughout the entire thesis process. In particular, the extent of her availability during such a busy, and at times stressful, period was much appreciated. I would also like to thank my academic supervisor Prof Mick Power for his succinct and helpful input. The Tayside paediatric diabetes team in its entirety were, in the first instance, welcoming and thereafter were unfalteringly helpful, particularly throughout the data gathering period, for which they deserve my grateful thanks. I would especially like to thank the team specialist nurses Sue, Val and Christine.

For all of the young people who considered participating in my study, and especially to those who chose to take part, I extend sincere gratitude.

Dr Jennifer Lonsdale deserves special credit for patiently gifting her expert statistical knowledge as well as the gift of time, precious as it is. Dr Eve Wilson and Dr Paula Mulholland too deserve grateful thanks for continued friendship as well as much appreciated understanding and support throughout the entire thesis extravaganza!

To Hazel and Eliot, the best siblings a girl could ask for, I extend grateful thanks for continued acceptance, friendship, support and understanding. Together with Benedict and Adam, you deserve special credit for continuing to provide me with the inspiration that we can succeed in life. Dad, thank you for the support you provided. Dave, I feel grateful that you persevered and would like to thank you, in particular for your selfless support during viva week.

Finally, I would like to acknowledge my good friend, Dr Donna Redford. I am so proud of you and all of your many achievements and in awe that you were always available to provide me with support, encouragement and understanding this last year in particular. I treasure your friendship and reiterate your sentiment that our journey through psychology over the last ten years would have been much less enjoyable without you there with me! I thank you.
Main Abstract

Objectives:

**Systematic review**: This article presents a systematic review of studies evaluating the evidence for mobile phone-based interventions with adolescents who have Type 1 diabetes. Studies were critically appraised and findings synthesised with the aim of answering the question: do mobile phone technologies facilitate improved outcomes in adolescents who have Type 1 diabetes?

**Empirical research study**: Diabetes research has indicated an association between attachment security and metabolic control as well as increased prevalence of mental health difficulties in diabetes populations. There is limited research with an adolescent Type 1 diabetes population. The current study aimed to examine attachment, emotional distress and self-esteem in an adolescent Type 1 diabetes population in relation to metabolic control and quality of life. The current study also aimed to evaluate the impact of ‘wellbeing text-messaging support’ with the same population.

Method:

**Systematic review**: A systematic search strategy was employed to identify relevant studies. An electronic database search, combined with a hand search of key journals and reference sections of key papers, was undertaken. Methodological quality was determined using an idiosyncratic measure including information relating to study design, sample size, interventions and statistical analyses. A narrative synthesis was performed due to the heterogeneity of the sample.

**Empirical research study**: 60 participants aged between 12-18 years old who had a diagnosis of Type 1 diabetes for over 12 months took part. A longitudinal questionnaire design was used to collect data using five validated psychological measures. HbA1c was used as a measure of metabolic control. Text-messaging comprised a wellbeing module delivered daily over a three-week period.

Results:

**Systematic review**: 12 eligible studies were identified. One achieved a rating of ‘very good’, two a rating of ‘good’ and the remaining nine were pilot and/or feasibility studies,
of whom four received a rating of ‘fair’ and ‘five received a rating of ‘poor’ methodological quality. Results indicated limited good quality evidence which included improved adherence and self-efficacy and mixed results in relation to metabolic control. Limitations identified included the use of small, convenience samples and short study duration.

**Empirical research study**: High levels of fearful attachment security predicted poorer metabolic control and poorer quality of life, and high levels of emotional distress predicted poorer quality of life. ‘Wellbeing text-messaging support’ resulted in significantly improved quality of life.

**Conclusion**:

**Systematic review**: There is limited evidence that mobile phone technology has consistently improved outcomes in adolescents with Type 1 diabetes. Due to the number of pilot or feasibility studies and predominantly poor/fair quality of the current literature, and the heterogeneity of the sample, only tentative conclusions can be drawn, thus highlighting the need for further research.

**Empirical research study**: Adolescent attachment style and emotional distress may be assessed as part of routine diabetes care in order to identify individuals who are potentially most at risk of failing to engage with diabetes health care. This can subsequently impact negatively on metabolic control and/or quality of life. These findings highlight the importance of clinical psychology input in paediatric diabetes teams. Further research in relation to text-messaging support was recommended.
1 Systematic Review

1.1 Abstract

Objectives:
This article presents a systematic review of studies evaluating the evidence for mobile phone-based interventions with adolescents who have Type 1 diabetes. Studies were critically appraised and findings synthesised with the aim of answering the question: do mobile phone technologies facilitate improved outcomes in adolescents who have Type 1 diabetes?

Method
A systematic search strategy was employed to identify relevant studies. An electronic database search, combined with a hand search of key journals and reference sections of key papers, was undertaken. Methodological quality was determined using an idiosyncratic measure including information relating to study design, sample size, interventions and statistical analyses. A narrative synthesis was performed due to the heterogeneity of the sample.

Results
12 eligible studies were identified. One achieved a rating of ‘very good’, two a rating of ‘good’ and the remaining nine were pilot and/or feasibility studies, of whom four received a rating of ‘fair’ and ‘five received a rating of ‘poor’ methodological quality. Results indicated limited good quality evidence which included improved adherence and self-efficacy and mixed results in relation to metabolic control. Limitations identified included the use of small, convenience samples and short study duration.

Conclusion
There is limited evidence that mobile phone technology has consistently improved outcomes in adolescents with Type 1 diabetes. Due to the number of pilot or feasibility studies and predominantly poor/fair quality of the current literature, and the heterogeneity of the sample, only tentative conclusions can be drawn, thus highlighting the need for further research.
1.2 Introduction

Diabetes mellitus is a highly prevalent and costly chronic health condition that can result in severe health-related complications including heart disease, stroke, amputation and blindness. There are two main types of diabetes, Type 1 and Type 2. Global prevalence has been estimated as 366 million in 2011 rising to 522 million in 2030 and prevalence of diabetes in the UK was estimated to be 4.45% of the population (2.9 million people) (1). According to a recent review, an estimated ten percent of all National Health Service (NHS) expenditure is on diabetes related care which was almost £14 billion in 2012 (1).

Type 1 diabetes usually appears before the age of 40 and develops if the body cannot produce insulin, a hormone that helps glucose to enter specific cells where it is used by the body as fuel. Although Type 1 diabetes is the least common of the two main types and accounts for around 10% of all people with diabetes, the vast majority of children and young people who have diabetes have Type 1 diabetes, and the peak age of diagnosis is reported as 10-14 years old (1). Prevalence rates for individuals with Type 1 diabetes have seen a steady increase in numbers, reflecting the rise in the incidence of diabetes in Scottish children, which is said to have risen by 2-3% per year since 1968 (2). Type 2 diabetes develops when the body is unable to produce enough insulin or when the insulin that is produced does not work properly (known as insulin resistance) and in most cases is linked with being overweight. Type 2 diabetes usually appears in people over the age of 40; however, more recently, children, some as young as seven, are being diagnosed with the condition (1).

The National Institute for Clinical Excellence (NICE) in collaboration with the National Collaborating Centre for Women and Children’s Health (NCCWCH) recommend an integrated and ongoing package of care for Type 1 diabetes (3). For children and young people that involves access to multidisciplinary team support towards a comprehensive management plan to include insulin treatment. Insulin treatment involves frequent self-monitoring of blood glucose towards optimal metabolic control, as measured by HbA1c (the recommended target for HbA1c is <58mmol/mol, International Federation of Clinical Chemistry units: IFCC) (3). Further, NICE and the Scottish Intercollegiate Guidance Network (SIGN) also recommend access to mental health professionals due to
the potential risk that psychological factors such as anxiety and depression, and family functioning, may have on diabetes management, wellbeing and quality of life (4).

Despite clear guidelines, strict glycaemic control is hard to accomplish for children and young people (5) and evidence indicates that this population have the worst rates of very high risk glycaemic control and of the acute metabolic complication diabetic ketoacidosis (DKA) (1), a potentially life-threatening complication that occurs predominantly in individuals who have Type 1 diabetes and can include symptoms such as vomiting, laboured breathing, dehydration, confusion and in some cases coma. However, there is clear evidence that good diabetes management can lead to fewer complications and lower morbidity and mortality (1).

It has been widely reported that metabolic control decreases significantly during the adolescent period (6-8) findings that have been replicated in Scotland (9). The adolescent period is defined by the World Health Organisation (WHO) as between 10-19 years of age and is characterised by a phase of rapid growth and development during which physical, sexual and emotional changes occur (10). It is thought likely that poor metabolic control may be attributable to some of the individual changes that occur during adolescence. It is important, therefore, to continually develop ways in which to facilitate improved diabetes self-management towards optimal glycaemic control, for the adolescent population in particular.

The recent introduction of telemedicine (TM) systems in healthcare has resulted in emerging support for the use of text messaging as a tool for behavioural change interventions for disease management and prevention (11). TM can be defined as a medical activity involving a component of distance and the use of a telecommunications approach (12). In relation to diabetes, two recent reviews found some evidence of improved glycaemic control following the provision of self-management health information via mobile phone in adults (13) and across the age range (14) in Type 1 and Type 2 diabetes. A further review of a range of health technologies found some improvement in diabetes self-management; however, there was limited evidence for improved glycaemic control following the use of mobile phones (15). It is important to note that a recent review of TM interventions that did not include mobile phones found
no improvement to glycaemic control or other aspects of diabetes management in Type 1 and Type 2 diabetes (12); in the same review, it was reported that the TM interventions did receive positive evaluations despite the considerable technical difficulties experienced and lack of positive health outcomes achieved. In summary, there is some evidence for the effectiveness of a range of TM systems, particularly mobile phones, in relation to diabetes self management and metabolic control, in mainly adult Type 1 and Type 2 diabetes populations; however there is a need for further investigation to clarify which aspects of TM interventions are most effective.

Evidence would suggest that mobile phone ownership among adolescents in the UK is significant. According to recent figures, over 90% of all teenagers (and almost 90% of 12-year-olds) now have a mobile phone (16). Of those, 74% regard text-messaging as their primary form of communication; therefore, text-messaging appears to have established itself as the adolescents’ preferred channel of basic communication.

The increasing numbers of young people developing Type 1 diabetes and widely reported difficulty adolescents in particular have in achieving optimal glycaemic control have led to the need for the current review. Together with emerging evidence for the potential use of TM systems in diabetes management and the prevalence of mobile phone use among adolescents, the objective of the current review was to evaluate the current literature relating to mobile phone technology. All of the studies included for systematic review involved the use of mobile phone technology to improve outcomes for adolescents who have Type 1 diabetes.

**Aim:** Do mobile phone technologies facilitate improved outcomes in adolescents who have Type 1 diabetes?
1.3 Method

1.3.1 Search strategy

A comprehensive electronic search was conducted for relevant articles published to date using the online databases Ovid MEDLINE, EMBASE, PsychINFO, Google Scholar and the Cochrane Library. The use of mobile phone technology in health care is quite novel therefore no time parameters were placed on the search.

Combinations of the following key words were used to inform the search: [mobile phone] or [cell or cellular phone] or [text-messaging or text or texting] combined with [diabetes or Type 1 diabetes or T1DM] and [adolescen*] in title/abstract/or as free text.

In view of increasing the sensitivity of the search, key journals (Paediatric Diabetes, Diabetes Technology & Therapeutics and the Journal of Telemedicine and Telecare, from 2004 - 2012) along with the reference sections of identified articles and most recent reviews (n=4) were hand searched to identify relevant articles.

The main authors of two poster presentations were contacted. One study had been submitted for publication and the authors declined to provide a draft for review. The second study was ongoing and was therefore not appropriate for review at the current time.

The review was conducted in English.

1.3.2. Inclusion and Exclusion Criteria

Inclusion criteria

- Participants had a diagnosis of Type 1 diabetes mellitus
- Participants included adolescents (up to 19 years)
- The study involved the use of mobile phone technology
- The study appeared in a peer-reviewed journal
Exclusion criteria

- Unpublished dissertations
- Conference presentations
- Articles not published in English

1.3.3 Assessing Methodological Quality

Once the papers were selected as potential sources of evidence, the methodology used in each study was assessed to ensure its validity. A quality rating form adapted from guidance outlined by the Scottish Intercollegiate Guidelines Network (17) was used. This was based on a number of key questions that focus on aspects of the study design shown to have significant influence on the validity of the results reported and conclusions drawn. SIGN has based its quality rating on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. Studies were rated on 10 items yielding a possible score of 20. Each paper’s total score was converted into a percentage to define a quality rating description of very good, good, fair, or poor.

All studies were examined by the author and 50% of the studies were randomly selected and rated independently by an experienced research assistant, using the same quality rating form. Disagreement between raters was resolved by discussion. The quality ratings are detailed in Table 1.
1.4 Results

1.4.1 Electronic database search

The process used to identify studies for the review is summarised in Figure 1. The Initial electronic search identified a total of 149 articles. Of these studies, 108 were either duplicates or deemed unsuitable for the review based on the information supplied in the title or abstract. 41 articles were reviewed in detail and a further 29 were excluded. The remaining 12 articles were deemed to have met criteria for inclusion in the current review.

1.4.2 Quality appraisal

Following systematic review, one study received a very good quality rating (18) and was deemed to provide strong evidence based on results. Two studies received a good rating (19, 20) and were judged to provide moderately strong evidence. Four studies received a fair rating, providing moderate evidence and five studies received a poor rating following appraisal. In particular the studies rated as poor were deemed to offer limited evidence based on study outcomes and any evidence was considered with caution.

It was expected that the sample studies would be too heterogeneous to be combined in a meaningful way, therefore a narrative synthesis was performed. The results are summarised according to the quality of the research, with consideration to feasibility of mobile phone-based intervention and outcome measures assessed.

1.4.3 Methodological Findings

In total 389 participants were included across study samples; 196 males and 193 females. All of the participants had a diagnosis of Type 1 diabetes mellitus and ranged in age from 7 to 19 years respectively. Small numbers were apparent in many of the studies and will be discussed in more detail in the methodological issues section.
Databases searched: Ovid MEDLINE(R), EMBASE, PsychINFO, the Cochrane database of systematic reviews, Google Scholar and hand searches.

Title and abstracts screened for suitability (n=149)

Excluded (n=108)
Duplicates removed and studies excluded from further evaluation on the basis of title and abstract.

Full text sought (including systematic reviews and meta-analyses) for further perusal (n=41). Full inclusion/exclusion criteria applied.

Excluded (n=29)
Reasons for exclusion
- Type 2 diabetes population (n=2)
- Parent of YP with diabetes (n=2)
- Adult population (n=7)
- No device/wrong type of device (n=3)
- Reviews or meta-analyses (n=5)
- Duplicates across databases (n=1)
- Qualitative (n=4)
- Posters (n=5)

Poster main authors contacted to request detailed article (n=2). Neither article was currently available.

12 studies satisfying inclusion/exclusion criteria, therefore included in research synthesis

Figure 1: Flow diagram of systematic search process and paper selection
Table 1. Author, design, outcome measures, key results and quality ratings in the studies included for systematic review

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Study design</th>
<th>Duration</th>
<th>Sample age and size</th>
<th>Outcome measures</th>
<th>Key results</th>
<th>Rating (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Franklin <em>et al.</em> 2006 UK</td>
<td>RCT</td>
<td>12 months</td>
<td>92 8-18 years Control CIT group</td>
<td>HbA1c  Self Efficacy for Diabetes  Diabetes Knowledge Assessment (DKN)  Diabetes Social Support Interview (DSSI)  SSI for satisfaction</td>
<td>No change to HbA1c in patients on CIT with or without Sweet Talk. Mean HbA1c improved in patients allocated to IIT and <em>Sweet Talk</em> (ST) (9.2±2.2%, 95% CI -1.9, -0.5, P&lt;0.001). Self-efficacy higher for CIT with ST than without (CIT alone 56.0±13.7, CIT with ST 62.1±6.6, 95%CI+2.6,+7.5, P=0.003) and improved self-reported adherence score (CIT alone 70.4±20.0, CIT with ST 77.2±16.1, 95%CI+0.4,+17.4, P=0.042) 82% of patients felt that Sweet Talk had improved their diabetes self-management and 90% wanted to continue to receive messages.</td>
<td>80</td>
</tr>
<tr>
<td>Rami <em>et al.</em> 2006 Austria</td>
<td>RCT</td>
<td>6 months (3 month crossover)</td>
<td>36 10-19 years</td>
<td>HbA1c  Satisfaction questionnaire</td>
<td>HbA1c improved during TM phase and deteriorated during PD phase: TM-PD HbA1c (%; median range): 9.05 (8-11.3) (at 0 months), 8.9 (6.9-11.3) (at 3 months), and 9.2 (7.4-12.6) (at 6 months), and PD-TM: 8.9 (8.3-11.6), 9.9 (8.1-11), and 8.85 (7.3-11.7) (p&lt;0.05). Satisfaction</td>
<td>55</td>
</tr>
<tr>
<td>Study Authors</td>
<td>Study Design</td>
<td>Timeframe</td>
<td>Age</td>
<td>Measures</td>
<td>Findings</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------</td>
<td>-----------</td>
<td>-----</td>
<td>--------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Tasker et al. 2007 UK</td>
<td>Cohort</td>
<td>1 month</td>
<td>37</td>
<td>Frequency of hypoglycemic episodes HbA1c Feedback questionnaire</td>
<td>Overall frequency of 5.2 hypos per month (all rated as mild) with no difference between method used (or male/female, pre-adolescents). No. of hypoglycemic episodes did not relate to HbA1c Marked preference for the mobile phone text messaging over the written diary method</td>
<td></td>
</tr>
<tr>
<td>Carroll et al. 2011a USA</td>
<td>Feasibility study</td>
<td>6 months</td>
<td>40</td>
<td>Usability and satisfaction</td>
<td>Technical issues noted by adolescents (74%) and parents (70%) Would choose this technology if available: adolescents (74%) and parents (85%) Adolescent reported activities and positive feelings about the technology (range 71-94%) Parental reported activities and positive feelings about the technology (range 63-80%)</td>
<td></td>
</tr>
<tr>
<td>Carroll et al. 2011b USA</td>
<td>Pilot</td>
<td>3 months</td>
<td>10</td>
<td>Diabetes self-management profile (DSMP) Cornell Parent Behaviour Description Scale (CPBDS) Paediatric Quality of Life scale (PedsQL) HbA1c</td>
<td>Self-management improvement from 55.2 (95% CI, 50.8-59.6) to 61.1 (95% CI, 55.5-66.7) (p&lt;0.01) HbA1c reduction from 8.1% (95% CI, 7.3-8.9%) to 7.6% (95% CI, 7.1-8.1%) (p&lt;0.04) CPBDS and PedsQL - difference ns</td>
<td></td>
</tr>
<tr>
<td>Mulvaney et al. 2012a USA</td>
<td>Pilot</td>
<td>3 months</td>
<td>23</td>
<td><strong>Baseline only (intervention group):</strong> Barriers to Diabetes Adherence (BDA) Self-Care Inventory (SCI) Self-efficacy for Diabetes Management Pre-post</td>
<td>Intervention group maintained HbA1c (8.8%, SD 2.1) and control group HbA1c worsened (to 9.9%, SD 2.3). Main effect of group = ns (p=0.4). Main effect of time, p=0.020, Interaction between group and time, p=0.006.</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Duration</td>
<td>Age</td>
<td>Measures</td>
<td>Outcomes</td>
<td></td>
</tr>
<tr>
<td>-------</td>
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<td>----------</td>
<td>----------</td>
<td></td>
</tr>
<tr>
<td>Mulvaney et al. 2012b USA</td>
<td>Feasibility study</td>
<td>10 days</td>
<td>12-17 years</td>
<td>HbA1c, Usability interviews</td>
<td>Usability and satisfaction with the system rated highly. 60% prefer to communicate via text messaging. Use of phones during school was variable; 25% reported the negative impact on diabetes-care due to limited phone access at school. EMA method: 58.9% of calls had data. Patterns of adherence identified: morning accounted for the majority of missed BG checks and insulin injections. Self report of adherence at baseline was related to EMA-reported missed BG checks ($rs=-0.32$, $p=0.023$) and missed insulin doses ($rs=-0.29$, $p=0.045$) but not timing of glucose monitoring or incorrect insulin dosing. Overall, EMA-reported adherence was not related to GC.</td>
<td></td>
</tr>
<tr>
<td>Cafazzo et al. 2012 Canada</td>
<td>Pilot</td>
<td>12 weeks</td>
<td>12-16 years</td>
<td>Daily frequency of blood glucose measurement (and number of rewards collected) Self-care Inventory (SCI) Diabetes family responsibility questionnaire (DFR) Diabetes Quality of Life for youth (QoL)</td>
<td>Frequency increased 50% (from 2.4 to 3.6 readings per day) ($P=0.06$) (Rewards detailed in article) HbA1c = ns (8.8%, SD0.74 – 9.2%, SD 1.03, $p=0.11$) SCI = ns DFR = ns QoL = ns (trend towards worsening)</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Design Type</td>
<td>Duration</td>
<td>Age</td>
<td>Measures</td>
<td>Findings</td>
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<tr>
<td>Schiel et al. 2011 Germany</td>
<td>Feasibility trial</td>
<td>3 days</td>
<td>16</td>
<td>HbA1c, Satisfaction interview</td>
<td>88% stated they would continue to use the system. Various aspects of physical activity were measured. In less than half of the participants (37.5%) there was direct correlation between physical activity and blood glucose values. High variability in individual reactions to the physical activity noted. High acceptance for the system reported.</td>
<td></td>
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<tr>
<td>Gammon et al. 2005 USA</td>
<td>Pilot and feasibility</td>
<td>4 months</td>
<td>15</td>
<td>Usability and satisfaction questionnaires and interviews</td>
<td>The system was easily integrated into everyday life; however, appropriateness reported to taper off with the onset of adolescence. Automatic transfer of BG rated positively. System helped parents to feel reassured (100%). User enthusiasm suggested there may be a consumer market regardless of positive health outcomes.</td>
<td></td>
</tr>
<tr>
<td>Carroll et al. 2007 USA</td>
<td>Pilot</td>
<td>3 months</td>
<td>10</td>
<td>Usability questionnaire</td>
<td>Participants reported the tool as easy to use and useful for diabetes management and as a tool to communicate with school but not parents or physicians.</td>
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</tr>
<tr>
<td>Hanauer et al. 2009 USA</td>
<td>Pilot and feasibility study</td>
<td>3 months</td>
<td>40</td>
<td>Current use of technology, Frequency of use including number of reminders sent; response to reminders; BG values submitted. HbA1c</td>
<td>Females more likely than males to be users, regardless of modality (p=0.04). Mobile phone users submitted more BG measurements than e-mail users (33.1 vs. 2.3 per user, p&lt;0.02). In both groups, over time submissions</td>
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</table>
Satisfaction questionnaire decreased. HbA1c = ns 50% of participants would choose to access the system using mobile phone.

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</table>
The studies took place in six different countries including two in the United Kingdom (UK), six in the United States of America (USA), and one in Canada, Austria, Germany and Norway.

1.4.4 Design and Comparisons

The review sample included two trials and ten observational studies, reviewed as cohort studies. One randomised controlled trial (18) and one randomised crossover trial (19) evaluated whether text-messaging support improved glycaemic control (18, 19) and self-efficacy and adherence (18) in paediatric patients with Type 1 diabetes. Another study employed a longitudinal mixed design to ascertain whether mobile phone technology and computer-based interviewing was feasible in assessing the frequency of symptomatic mild hypoglycaemia (20). The remainder of the studies were described as pilot studies (21, 22, 23, 24, 25), feasibility studies (26, 27, 28) or both pilot and feasibility studies (29) and were primarily designed to pilot novel technology, to measure feasibility and to ascertain whether the technology could support aspects of diabetes management. Three of the sample studies measured usability only (23, 25, 28) and almost all of the studies measured participant satisfaction. See Table 2 for a description of the mobile phone technologies included for review.

Seven of the studies matched participants on age, gender and HbA1c (18, 19, 20, 21, 22, 27, 29) and a range of studies matched participants on BMI (18, 19) and duration of illness (18, 19, 27, 29). Two of the remaining four studies used small convenience samples (10 each respectively) that were not matched (23, 24) and two studies employed small volunteer samples that were not matched (26) in terms of gender, duration of illness or level of phone use (25).
Table 2. The mobile phone technology used in the studies included for systematic review

<table>
<thead>
<tr>
<th>Author</th>
<th>Technology required</th>
<th>Frequency</th>
<th>Equipment supplied</th>
<th>System and delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Franklin <em>et al.</em> 2006 (18) UK</td>
<td><em>Sweet Talk</em> Mobile phone SMS</td>
<td>Daily</td>
<td>Yes</td>
<td>Goals set during routine clinic visits were reinforced by daily messages via SMS using the novel <em>Sweet Talk</em> system. Messages were tailored to patients’ age, gender and insulin regimen and contained goal-specific prompts. The system data base included 400 messages that encompassed the four main diabetes self-management tasks: insulin injections, BG testing, healthy eating and exercise. Other categories included carbohydrate counting and pump therapy.</td>
</tr>
<tr>
<td>Rami <em>et al.</em> 2006 (19) Austria</td>
<td><em>VIE-DIAB</em> Mobile phone SMS</td>
<td>Daily</td>
<td>Yes</td>
<td>During the TM phase of this crossover trial, participants sent data (including date, time, blood glucose, medication, hypoglycaemic events) at least once per day or each time they measured a blood glucose value. Once weekly they received an automatically generated SMS message if no changes to treatment were indicated or a personalised message with specific advice if insulin adjustment was required. Participants also continued their diary notes during the TM support phase, for safety reasons.</td>
</tr>
<tr>
<td>Tasker <em>et al.</em> 2007 (20) UK</td>
<td><em>Sweet Talk</em> (see Franklin <em>et al.</em>, 2006) Mobile phone SMS Internet/e-mail</td>
<td>Daily</td>
<td>No</td>
<td>The ‘mobile phone’ group were sent a daily reminder via SMS to ask for information relating to the number of hypoglycaemic events (previously defined) that they had experienced. The ‘computer-based interviewing’ group (CBI) received an e-mail to log onto the CBI system to complete the same questions.</td>
</tr>
<tr>
<td>Study Authors</td>
<td>Study Year</td>
<td>Country</td>
<td>Study Type</td>
<td>Mobile Service</td>
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</tr>
<tr>
<td>Mulvaney et al.</td>
<td>2012 (27)</td>
<td>USA</td>
<td>Feasibility</td>
<td>Telesage Mobile phone</td>
</tr>
<tr>
<td>Hanauer et al.</td>
<td>2009 (29)</td>
<td>USA</td>
<td>Pilot and feasibility</td>
<td>CARDS Mobile phone SMS E-mail Internet</td>
</tr>
<tr>
<td>Cafazzo et al.</td>
<td>2012 (21)</td>
<td>Canada</td>
<td>Pilot</td>
<td>bant Mobile phone Wireless</td>
</tr>
<tr>
<td>Mulvaney</td>
<td></td>
<td></td>
<td></td>
<td>SuperEgo</td>
</tr>
<tr>
<td>Authors</td>
<td>Year</td>
<td>USA</td>
<td>Study Type</td>
<td>Devices</td>
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<tr>
<td>et al.</td>
<td>2012 (22)</td>
<td>Pilot</td>
<td>Mobile phone, Internet</td>
<td>ascertained barriers to adherence using the SuperEgo system. Individual messages could be viewed in each participant’s web page and, using their mobile phone, participants could add or search for messages, change or reschedule messages. Messages could also be specified as private or public and could be viewed by or used by others in the study.</td>
</tr>
<tr>
<td>Carroll et al. 2007 (23)</td>
<td>USA</td>
<td>Usability</td>
<td>HealthPia GlucoPack TM</td>
<td>Yes</td>
</tr>
<tr>
<td>Carroll et al. 2011 (28)</td>
<td>USA</td>
<td>Feasibility</td>
<td>HealthPia GlucoPack TM</td>
<td>Yes</td>
</tr>
<tr>
<td>Carroll et al. 2011 (24)</td>
<td>USA</td>
<td>Pilot</td>
<td>HealthPia GlucoPack TM</td>
<td>Daily</td>
</tr>
<tr>
<td>Shiel et</td>
<td>DiaTrace</td>
<td>Study</td>
<td>Yes</td>
<td>A sensor to measure aspects of physical activity was integrated into a mobile phone</td>
</tr>
<tr>
<td>Study</td>
<td>Location</td>
<td>Device</td>
<td>Frequency</td>
<td>Feedback</td>
</tr>
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<tr>
<td>al. 2011 (26) Germany</td>
<td></td>
<td>Mobile phone</td>
<td>period of 3 days</td>
<td></td>
</tr>
<tr>
<td>Gammon et al. 2005 (25) Norway Pilot</td>
<td></td>
<td>Mobile phone Wireless system</td>
<td>Daily</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Key: SMS – short messaging service or text-messaging  
BG – blood glucose  
TM – telemedical  
CBI – computer-based interviewing
1.4.5 Outcome measures

In addition to the diversity of mobile phone technologies in the sample studies, a range of outcome measures was used (see Table 1). These included metabolic control (as measured by HbA1c) and a selection of questionnaire- and interview-based methods, detailed as follows.

**Metabolic control**

HbA1c monitoring is the most useful and widely used measure in evaluating metabolic control (30). This is reflected in the current sample which included an outcome measure of HbA1c in nine of the twelve studies (18, 19, 20, 21, 22, 24, 26, 27, 29). One further study referred to HbA1c in the study abstract as a non-significant result; however, this was primarily a feasibility study and there appeared to be no reference to its use as an outcome measure in the main article (28).

**Adherence**

Adherence was measured in five of the sample studies and included a number of validated measures such as the Diabetes Knowledge Assessment Scales (DKN: 31) alpha-reliability 0.83 and the Diabetes Social Support Interview (DSSI: 32) alpha-reliability 0.72-0.97 (both 18), the Diabetes Self-management Profile (DSMP: 33) alpha-reliability 0.76 (24) and 6 items only from the Diabetes Behaviour Rating Scale (DBRS: 34) alpha-reliability 0.73 (27). The Barriers to Diabetes Adherence (BDA: 36) (22) and Self-Care Inventory (SCI: 36) alpha-reliability 0.87 (21, 22) were also used to measure adherence.

Ecological momentary assessment (EMA) is the sampling of behaviours and experiences in real time using mobile devices (37). EMA was used to measure adherence behaviours including blood glucose monitoring and insulin management (27).

**Self-efficacy**

Self-efficacy was measured in two of the sample studies. The self-efficacy for diabetes scale (SED: 38) alpha-reliability 0.9 was used on both occasions (18, 22).
In one study, it appeared that three measures, of adherence (SCI: 36; BDA: 35) and self-efficacy (SED: 38), were used with the intervention group at baseline only. No conclusions were reported regarding adherence or self-efficacy as a result of the particular intervention in this study (22).

**Quality of Life**
Quality of life was measured in two of the studies using the Paediatric Quality of Life Diabetes module (PedsQL: 39) alpha-reliability 0.77 (24) and the Diabetes Quality of Life for Youth scale (40: 21).

**Family-related measures**
Two of the sample studies involved the use of family-related outcome measures including The Cornell Parent Behaviour Description Scale (41: 24) and the Diabetes Family Responsibility Questionnaire (42: 21) alpha-reliability 0.81-0.85.

**Satisfaction or feasibility**
Usability was the only outcome measured in three of the sample studies (23, 25, 28). Overall, nine of the studies included a measure of satisfaction or feasibility/usability: of those, an interview technique was used in four studies (18, 21, 22, 29) and questionnaires were used in five (19, 20, 23, 25, 28).

**Various**
There were a number of other outcome measures in the sample studies. These included the measurement of frequency of symptomatic mild hypoglycaemia (20); the reported measurement of mobile phone/technology use at baseline (27, 29); the frequency with which study technology was used to record blood glucose (21) and number of logins/reminders/responses (29); the use of a sensor to measure aspects of physical activity (26); and the level of engagement with the technology as measured by the number of rewards collected (21).

The review sample included an array of outcome measures, making a formal, quantitative synthesis impractical.
1.4.6 Methodological Issues

1.4.6.1 Sample characteristics
All of the participants were recruited through diabetes clinics. The sampling procedures and sample sizes varied considerably and require consideration in the context of methodological limitations. The sampling procedures in particular were, in some of the studies, not clearly defined (19, 22) and in one study there was no recruitment method provided (26) rendering these studies difficult to replicate. Further, the number of eligible participants was defined in only four studies (18, 20, 23, 25). This allowed the calculation of the participation rate and therefore the likelihood of selection bias; one study detailed a ‘volunteer’ sample of 10 from a possible 800 participants, indicating an extremely large difference and therefore a significant degree of selection bias (23). The results of this particular study should therefore be considered with considerable caution. Information relating to the number of eligible participants was not available in the remaining eight studies, therefore the participation rate could not be calculated and the potential level of selection bias that may have influenced any conclusions reached was not directly calculable. These studies also require some caution when considering their findings.

Overall, seven of the studies labelled their samples as ‘convenience samples’ (21, 22, 23, 24, 27, 28, 29) and a further two study samples were labelled as ‘volunteers’ (25, 26). The use of convenience and volunteer samples are particularly important since selection or sampling bias may be introduced with their use which can potentially impact upon the external validity of the study findings and in doing so limit the generalisability of the results. Further, of the convenience and volunteer samples, participant numbers were particularly low ranging from 10 to 50 (median 16) and there were concerning high rates of attrition reported in two studies (27.5%: 29; 40%: 21), with limited information provided relating to the reasons why participants dropped out or reported effort to follow up the participants that dropped out. The sampling procedures used and sample sizes would suggest evidence of sampling bias that may likely have impacted on the external validity and generalisability of the findings; therefore, some care should be extended when study outcomes are being considered.

All of the studies specified provided inclusion/exclusion criteria in relation to age and diagnoses. Of those, six studies specified a diagnosis of Type 1 diabetes for over one year.
This is particularly important in diabetes research since a 12-month period following diagnosis is recommended when researching metabolic control due to the potential effects of residual pancreatic activity on metabolic control as well as adherence behaviours during this time (43, 44). Exclusion criteria included serious social problems, severe learning disability and needle phobia (18), abnormal cognitive development and no other chronic diseases except well-controlled asthma (23, 24, 28) and well-controlled hypothyroidism (28). The assessment of cognitive functioning is important when conducting research to ensure capacity. Ethically, participants are required to fully understand the implications of participating in research in order to provide informed consent. Also, in relation to cognitive functioning, evidence would suggest that it can rapidly decline when blood glucose levels become too high or too low (45); therefore research involving any diabetes population should ideally include ongoing blood glucose monitoring to potentially avoid reduced cognitive functioning as a confounding variable and of course to make sure individuals are receiving appropriate care at all times. It is also important to note that none of the studies expressly excluded a diagnosis of psychiatric disorder. This may be important since acute mental health difficulties have been found to be strongly associated with decreased metabolic control (46, 47), therefore the study samples may have potentially been confounded.

1.4.6.2 Design characteristics
In eight of the studies, the participants were provided with mobile phones and other relevant technology for the duration of the study (18, 19, 21, 22, 27). In the remaining four studies, participants were required to have access to a mobile phone and/or the internet (20, 22, 27, 29). The requirement for the use of the internet impacted upon some participants who were unable to access the internet at any given time, resulting in some missing data which was discussed as a potential limitation in one study (20). Thus, the requirement for access to suitable technological equipment or internet access as part of a study design may exclude a cohort of individuals who do not have access to technology, may act as a barrier for those who have variable access to technology and in doing so lead to missing data and limit the validity and generalisability of the findings.

The use of novel technology may increase the motivation to engage with an intervention, at least initially, potentially biasing any outcome over a short time frame. Evidence for
this type of bias was reported in one study where significant reduction in the use of the technology was indicated after one month, and consistently over the three month study period (29). As reported, many of the studies included for review took place over a short time period; therefore may have been influenced by this type of bias as a result.

Other potential confounding variables identified by one study (27) included the assumption that all young people own and are conversant in the use of mobile phones and other technology. One of two studies gathered information relating to individuals’ mobile phone experience prior to taking part and found participant experience differed greatly within their study sample (25), which may have impacted on the study outcomes.

Another study in which blood glucose monitoring and insulin management was measured as an outcome identified the assumption that adolescents knew how and when to check their blood glucose as a potential confounding variable (27).

The technology systems in many of the sample studies were not fully integrated into clinical environments, a limitation identified by Carroll et al. (24). Therefore, further more robust studies were recommended to establish clinical efficacy.

1.4.6.3 *Intervention characteristics*
In the sample studies, the length of intervention varied considerably ranging from 3 days to 12 months (median 3 months). The trials lasted for 12 and 6 months respectively. Of the remaining cohort studies, the length of interventions included 6 months, 4 months, one month, 10 days and 3 days and five studies were of 3 months duration. In particular, the majority of the pilot/feasibility studies involved relatively short time frames. As identified, there was potential evidence of bias as a result of novelty value over a short study time period (29); therefore, further research to ascertain whether findings persisted over a longer time frame was indicated.

The technology included for review (see Table 2) was extremely diverse; therefore any evidence has been considered on the basis of the quality rating of each individual study which will be summarised in the synthesis of findings. As reported the majority of the studies measured participant satisfaction with the technology. Of those, one study used rewards, to encourage regular blood glucose monitoring (21) which may have impacted
upon participant satisfaction ratings; thus, acting as a confounding variable. Participant satisfaction was rated highly in one study despite no evidence of positive health outcomes and the authors considered that this level of satisfaction may have indicated a market for the new technology even in the absence of positive outcomes (25). The technical problems reported in some of the studies (19, 28) may have impacted upon the collection of data leading to missing data.

1.4.7 Power calculations

The two trials reported a sample size calculation based on power (18, 19) and their study samples appeared sufficient in size, significantly reducing the likelihood of a Type II error. The feasibility/pilot trials did not need to include sample size calculations.

1.4.8 Statistical Analyses

Various statistical analyses were conducted across the sample studies. The statistical packages used for analyses were provided in four of the studies (19, 24, 26, 29). One of the trials reportedly analysed data in keeping with the intention-to-treat principle and reported the use of ANCOVA, t-tests, chi square and Wilson’s method analyses (18). The other trial used a linear mixed model of association (19).

The remaining studies used correlation analyses (20, 26, 27), trajectory analysis (27), ANOVA (22) and t-tests (29) and qualitative themed analysis was used in three studies (22, 24, 25). Descriptive analysis was the primary form of analysis in six of the studies, which was deemed appropriate for pilot/feasibility studies (20, 21, 23, 25, 27, 28) and in relation to satisfaction in four studies (18, 19, 21, 29).

One trial supplied data on non-respondents and reported no difference between those who did not supply data and those who did, which was deemed to indicate a well conducted study according to the quality criteria (19).
1.4.9 Comparison with earlier reviews

The current review focussed specifically on mobile phone interventions with an adolescent population who had Type 1 diabetes in order to identify whether there was evidence that the use of mobile phone support resulted in positive health outcomes with this population. As reported, there were four earlier reviews relating to telemedical interventions with diabetes populations; however, due to the diversity of the studies included in each review, particularly the amalgamation of Types 1 and 2 diabetes across a number of the individual studies as well as the combining of ages ranging from adolescence and younger to adult, a comparison of the evidence would not provide particularly firm conclusions or generalisable information for a specific population. To clarify, two of the earlier reviews specifically evaluated mobile phone interventions (13, 14); however the remaining two studies included a range of other telemedical interventions in addition to mobile phones such as self-monitoring devices and wireless technology (12, 15). Of the two reviews that evaluated mobile phone technology, both included studies involving a mixture of participants with Type 1 and Type 2 diabetes and one review also included participants who were obese (14); similarly, many of the individual studies included participants representing all age categories, thereby reducing the generalisability of the findings in relation to specific diabetes populations. As previously discussed, metabolic control is known to decrease significantly during the adolescent period, therefore the studies that involved a range of ages may include confounded data due to the known impact that age can have on metabolic control.

Considering the aforementioned diversity within the mobile phone reviews, it was reported that, overall, the mobile phone interventions appeared to result in significant improvement to metabolic control (measured using HbA1c), with one study stating that that there was strong evidence to suggest significantly greater improvement in HbA1c in individuals with Type 2 diabetes compared with Type 1 diabetes (13). This particular finding is in contrast with the outcome of the current review, where there was mixed evidence in relation to improved HbA1c in adolescents with Type 1 diabetes; the inclusion of participants with Type 2 diabetes may have led to the overall significant findings in relation to improved HbA1c or perhaps evidence has been provided for improved HbA1c in non-adolescent diabetes populations following the use of mobile
phone support. More specific research that separates Type 1 and Type 2 diabetes populations, focussed on a particular age range, would be useful in determining whether mobile phone interventions can consistently result in improved outcomes for Type 1 or Type 2 diabetes populations and at different ages.

Of the four earlier reviews, there were some similarities with the current review that are important to note, in that there were a large number of technical innovations and diverse interventions reported in each review. Synthesising the findings in relation to what exact technology, or aspects of technology, resulted in improved outcomes for diabetes populations therefore remains a relatively challenging task. There was also feasibility for the use of this type of intervention reported in the majority of the studies, whether or not improved health outcomes were reported which was consistent with the findings of the current review.

1.4.9 Synthesis of findings

Following systematic review, there was limited good quality evidence for the use of mobile phone technology to improve outcomes for adolescents with Type 1 diabetes. Of the studies that were deemed to provide good quality evidence, the findings were mixed in terms of health outcomes. Strong evidence was found for the positive impact of individualised support received via text-messaging with significant improvement in self-efficacy (Conventional Therapy (CIT) 56.0 ± 13.7, CIT with Sweet Talk 62.1 ± 6.6, 95% CI+2.6,+7.5, P=0.003) and adherence (CIT 70.4±20.0, CIT with Sweet Talk 77.2±16.1, 95% CI+0.4, +17.4, P=0.042) and no evidence of improved glycaemic control (10.3 ± 1.7 vs. 10.1 ± 1.7%; all 18). Moderately strong evidence was found for personalised weekly advice received via text-messaging, based on information provided daily, that resulted in significant improvement to glycaemic control [% median (range)]; 8.9 (8.3-11.6), 9.9 (8.1-11), and 8.85 (7.3-11.7) (p<0.05) (19). A further good quality study compared text-messaging and computer-based interview (CBI) to produce moderately strong evidence for the use of telemedicine (TM) systems to measure the prevalence of mild hypoglycaemia in adolescents with Type 1 diabetes (20).
The quality ratings limit the standard of evidence for the individual technologies and outcomes in the remaining studies and indicate the need for further, more methodological, research in this area. As a result, the following evidence should be considered with a degree of caution and in the context of the methodological issues detailed earlier.

In two studies that were deemed to provide moderate evidence, some positive effects to glycaemic control (22, 24) and significant improvement in diabetes self-management were found (24). This followed the use of a glucose monitoring system (the usability of which was assessed in related studies, 23, 28) to support a behavioural contract agreed by young people and their parents (24); and following receipt of daily individually-tailored text messages (22). The most evident methodological limitations for these studies include the use of small, convenience samples (ten and twenty three respectively) and the short study time frames, significantly limiting the generalisability of the results.

Further, moderate evidence suggested feasibility in the use of technology to measure adherence behaviours and novel insight into adherence patterns (27); and feasibility of the technology used (28). Additional methodological limitations apparent in these studies included high levels of missing data, possible response bias and the reported level of individuals’ phone restrictions (27).

The remaining five studies were awarded a poor quality rating therefore they offer extremely limited evidence for any of the outcomes measured. The following summary should be considered with significant caution. All of the studies were concerned with piloting novel mobile phone interventions and measuring usability. One study measured usability only (23); text-messaging was preferred as a blood glucose monitoring system in comparison with e-mail (29); the use of an ‘mHealth app’ with a reward system led to an increase in the average frequency of blood glucose measurement and no change to HbA1c (21); the use of a sensor to measure physical activity offered limited evidence of a relationship with HbA1c (26); and the transfer of adolescent blood glucose measurement to parents’ mobile phones led to parental enthusiasm and some evidence of reduced parental anxiety but no evidence of improved health outcomes (25).

Overall, the feasibility of the mobile phone interventions with an adolescent diabetes population was indicated in all of the studies included for review (see Table 2). Most of
the studies suggested that the individual systems were technically possible to implement and there was some acknowledgement of the potential for inexpensive intervention (18, 29); in contrast, potential level of cost was recognised as an important factor to consider in one study (20). There were also technical issues reported with some of the systems (19, 28).

There appeared to be some agreement that the adolescent cohorts found the technology easy to use (22, 23), were easily trained in the use of new technology (29) and high acceptance of the different types of technology was reported (26). Satisfaction with the new technology was reported as high in the majority of the studies. One study suggested that there may be a consumer market for this type of technology, regardless of whether or not they improve health outcomes, such was the level of participant enthusiasm (25). However, moderately strong evidence found that some of the adolescents did report limited use of mobile phones to support diabetes self management (27).

Some of the novel technology has demonstrated the potential to facilitate access to new, useful information relating to symptoms common to diabetes, such as the greater frequency of hypoglycaemic episodes than previous research had shown (20), patterns of adherence (27) and the rapid diminishing interest in some of the new technology across time (29). This type of information may inform clinical care as well as towards the development of technology-based interventions.

To summarise, there may be potential to elicit positive health behaviours or improve outcomes for adolescents who have Type 1 diabetes using mobile phone technology; however, at present there is a lack of good quality evidence and therefore a need for further, more robust trials before any firm conclusions can be reached.

1.4.10 Critical Appraisal

Trials
In the two trials (18, 19), the participants were reportedly randomly allocated. An acceptable method of randomisation was reported in one study (18), however there was no detail of the technique used in the remaining trial (19). There was therefore no way to
evaluate whether an acceptable or unacceptable randomisation method has been used and whether or not this may have impacted upon the study outcomes. Blinding was not appropriate for use in either trial. In both of the trials, the participants were matched on age, gender, HbA1c, body mass index (BMI) and duration of illness indicating comparable groups of participants. Further, both trials reported sample size calculations based on power that indicated study samples were sufficient in size and reportedly data was analysed in keeping with the intention-to-treat principle. In presenting their results, the p-value was used in both trials and the confidence interval (95%) was provided in one study (18). In summary, both trials were predominantly conducted with consideration given to the mechanisms known to control bias in Randomised Controlled Trials (RCTs).

Observational studies
The ten remaining studies were reviewed as cohort studies. Of those, five studies matched participants on the basis of age, gender and HbA1c (20, 21, 22, 27, 29) and in two studies on the basis of duration of illness (27, 29). Two studies used small convenience samples (10 each respectively) that were not matched (23, 24) and two studies employed small volunteer samples that were not matched (26) in terms of gender, duration of illness or level of phone use (25). Some caution is required when interpreting the results of studies in which the participants were not matched; it should be noted, however, that overall all of the study samples included clear eligibility criteria in that they involved adolescents who had a diagnosis of Type 1 diabetes who were all seen regularly within diabetes clinics.

There was evidence of sampling bias in nine of the ten observational studies (21, 22, 23, 24, 25, 26, 27, 28, 29) following the use of convenience or volunteer samples as well as a lack of information relating to the number of eligible participants from which the study samples were selected or volunteered; information relating to the number of eligible participants was available in only three observational studies (20, 23, 25). In addition, the participant numbers were extremely low (ranging from 10 to 50: median 16) and concerning high rates of attrition were reported in two studies (27.5%: 29; 40%: 21). The sample characteristics and use of sampling in this way likely significantly impacted upon the external validity of the outcomes of the studies, considerably limiting the generalisability of the results.
Trials and observational studies

The majority of the sample studies addressed a clear and well defined question relating to mobile phone related telemedical interventions and all of the studies provided clear inclusion/exclusion criteria relative to the adolescent age population and Type 1 diabetes diagnoses. In relation to potential confounding variables, of those, only six studies specified a diagnosis of Type 1 diabetes for over one year (18, 19, 20, 21, 22, 27). This is important in diabetes research due to the potential effect that residual pancreatic activity can have on metabolic control as well as adherence behaviours during the ‘honeymoon’ phase, which can last for approximately 12 months following diagnosis. Without the specified length of diagnosis in the remaining studies, or indeed the identification of the importance of this particular period, pancreatic activity may potentially have confounded the data. Similarly, it is important to consider that none of the studies included, or made reference to, the importance of a diagnosis of psychiatric disorder as criteria for exclusion. There is evidence to suggest that acute mental health difficulties are strongly associated with decreased metabolic control (46, 47) therefore, without this information, it is possible that the study samples may potentially have been confounded. One study identified the assumption that all young people are experienced in the use of mobile phones as a possible confounding variable. Relative to this, two studies gathered data in relation to individuals’ mobile phone experiences prior to them taking part in their respective studies and one found it differed to quite an extent (25).

In eight of the studies, the participants were provided with the relevant technology to take part (18, 19, 21, 23, 24, 25, 26, 28). In the remaining four studies (20, 22, 27, 29), the participants were required to have access to relevant technology as criteria for inclusion. There was a reported impact on some of the participants to have access to for example the internet at a specific time, which was discussed as a possible limitation in one study (20) in that it may have resulted in missing data, limiting the validity and generalisability of the findings. It is possible this type of inclusion criteria may act as a barrier to some individuals who have variable access to technology or exclude a cohort of individuals who have no access to technology.
The use of novel technology was found to increase participant motivation to engage with an intervention in the short term (29). This type of bias may have influenced the outcome on a number of the sample studies due to the short time periods that were evident. Further, research was recommended to ascertain whether findings persisted over a longer time period.

The outcome measures were clearly defined in the majority of the studies included for review and many included information relating to the reliability and validity of each measure, where appropriate. There were exceptions, however, for example no alpha-reliability was reported for some of the outcome measures in the studies as follows (BDA, 22; Diabetes QoL for Youth, 21; The Cornell Parent Behaviour Scale, 24). In one study that primarily measured feasibility, HbA1c was referred to as a non-significant result when there appeared to be no reference to it as an outcome measure in the main article which was misleading and should be considered with significant caution (28). In another study, two measures of adherence and a measure of self-efficacy appeared to be used at baseline only which was confusing for the reader although the authors did not arrive at any firm conclusions regarding adherence or self-efficacy (22).

In summary, of the ten observational studies included for review, five were rated as ‘poor’ quality, therefore significant caution was suggested when considering the study outcomes, and four studies were rated as ‘fair’, and were therefore deemed to provide moderate quality evidence. These ratings were awarded following critical appraisal due to evidence of sampling bias, following the extensive use of convenience and volunteer samples, low participant numbers, the lack of information relating to the number of participants eligible for inclusion and some evidence of concerning rates of attrition. There were also a number of potential confounding variables identified such as the lack of information relating to length of diagnosis in six of the twelve studies included for review; none of the study samples excluded participants on the basis of diagnosis of a psychiatric disorder despite the known potential impact on metabolic control in individuals with diabetes; and technology bias, following the possible impact to motivation to engage with novel technology.
Positively, all of the studies included for review included a clear, well defined question relating to telemedical interventions and included the same adolescent, Type 1 diabetes population. The two trials were both conducted according to the main principles associated with good quality RCTs, in that they were randomised, though clear information relating to the randomisation method used was only evident in one of the trials (18). Further, comparable groups of participants were evident due to matching, for example on the basis of age and gender, there was evidence that the studies were suitably powered, analysis was reportedly completed in keeping with the intention-to-treat principle and the study results were clearly and appropriately presented. Overall, the outcome measures were clearly defined and their reliability, as measured by other sources, provided by the majority of the studies. Finally, the technology allowing participation was provided in the majority of the studies, minimising the exclusion of individuals who could not easily gain access to relevant technology.
1.5 Discussion

The systematic techniques used in this review to examine the current literature have revealed that mobile phone technology does appear to have some potential towards effective intervention with adolescents who have Type 1 diabetes; however more and better quality research is needed in this area. Overall, the quality of the research was varied, ranging from poor to very good and, as a result, the current evidence was considered extremely limited; this has supported a recent synthesis in which telemedicine research in general was considered weak and contradictory (48). In summary, there was some evidence of improved adherence and self-efficacy and mixed evidence for improved glycaemic control, following receipt of personalised text messages; text-messaging may also be used to measure the frequency of hypoglycaemic episodes. More robust trials to include larger cohorts and across longer periods of time was indicated.

The type of information provided to participants may have impacted upon the outcomes achieved and again further investigation is required. The provision of tailored diabetes-specific advice based on self-management goals set during clinic visits (18) and following data provided by participants on a daily basis (19) resulted in evidence of positive outcomes. Thus, self-efficacy and adherence were influenced by goal-specific information encompassing the four main areas of diabetes management (insulin injections, blood glucose testing, healthy eating and exercise) and HbA1c appeared to have been more influenced by timely feedback based on up-to-date participant data. This distinction requires further investigation for clarification.

Feasibility for the use of technology with the adolescent diabetes population was reportedly demonstrated in all of the studies included for review, despite the detailed limitations including the use of small, convenience samples and short time periods as well as the diverse range of technology used and noted technical difficulties. This provided additional support for the feasibility of mobile phone and other telemedical interventions reported by earlier systematic reviews (12, 13, 14, 15) that included a combination of Type 1 and Type 2 diabetes populations across the age range. Following the current review, it could be speculated that mobile phone technology may be suitable for use with an adolescent diabetes population. The evidence suggested that the adolescents found the technology easy to use (22, 23) and were trained without difficulty (29) and these
findings are supported by up-to-date data on adolescent mobile phone use, with 90% of adolescents sending and receiving texts on a daily basis (16). However, there was some evidence to suggest the limited use of mobile phones to support diabetes self management (27) and, in one study, parental opinion was that intervention appropriateness tapered off with the onset of adolescence (25); therefore, the ease with which the technology appears to have been used and the limited evidence for positive outcomes may indicate that although mobile phones are used with frequency within a ‘social’ context, they may not be used as readily for health care purposes by an adolescent diabetes population. This would of course be useful to ascertain since this may impact upon any concrete conclusions regarding the feasibility of the technology for use in health care.

Similarly, participant satisfaction with the technology was reportedly high in many of the studies. However, as reported, in some studies, motivation for use may have been influenced by the provision of new technology as well as the use of rewards (21; 28) with speculation that there may be a market for this type of novel technology whether or not efficacy can be demonstrated (25). Further, despite the possible novel technology ‘bias’, there was also evidence that participant interest waned over a very short period of time (29). Again the need for further research was indicated, in particular over a longer period of time than was apparent in the majority of the studies included for review.

In the current review, some of the studies failed to control for age, in that the age range spanned from 7 – 19 years old, respectively, with some including data from young children and adolescents in the same comparisons. Given the large evidence base regarding the significant decrease in metabolic control during the adolescent period (6-9), the variance in age across these studies may mean that the results are potentially confounded by the different developmental stages in which the children were involved. Thus, more caution should be extended towards some of the studies included for review.

The current diabetes care guidelines (3,4) recommend a comprehensive package of multi-disciplinary care to include insulin therapy and access to mental health professionals, due to the increased risk of mental health difficulties in the diabetes population and the potential impact upon diabetes self management, wellbeing and quality of life. Many of these guidelines were reflected in the array of outcome measures included in the current
review such as metabolic control (HbA1c), adherence, self-efficacy and the use of family-related measures. Quality of life was also included as an outcome measure in two studies which supports care guidelines as well as current literature, where health-related quality of life has emerged as an important health outcome in diabetes research (39). In relation to mood and anxiety disorders, evidence would suggest increased prevalence in an adolescent diabetes population in comparison with adolescents without diabetes (49-51); however, despite this, and the concerns reflected in the current care guidelines, none of the sample studies included a measure of mood or anxiety. Elevated levels of mood and/or anxiety offer a potential confounding variable in the sample population; therefore future research may consider the use of mood or anxiety measures to examine any potential impact.

In the context of current care guidelines (3, 4), emphasis has been placed on the increased risk that diabetes may have on individual wellbeing and quality of life. Research to include wellbeing support and a measure of quality of life was considered important for future research; this informed the text-messaging component of the following study.

1.6 Conclusion

With the increasing prevalence of Type 1 diabetes in children and young people and the costs incurred both in terms of individual health and wellbeing as well as monetary costs, and the well documented decrease in metabolic control during adolescence, there is a need for further good quality research to find effective and cost-effective ways to facilitate improved diabetes self-management towards better health outcomes. Telemedical (TM) interventions, in particular mobile phone systems, potentially offer an innovative way to support adolescents through the daily challenges faced in the self-management of diabetes. However, future research is required to ascertain whether mobile phones can successfully be utilised as tools for positive change within a health care environment or whether adolescents' mobile phone use will remain predominantly a social tool.
1.7 References


2 Aims and Hypotheses

2.1 Aims

The context for the current study includes the increasing prevalence of Type 1 diabetes in children and young people, and the resultant costs incurred in terms of individual health and wellbeing as well as monetary costs. Further, the current care guidelines recommend access to mental health care, due to the increased risk of psychological difficulties and the potential impact to the wellbeing and quality of life in diabetes populations (The National Institute for Clinical Excellence (NICE: CG15, 2004); Scottish Intercollegiate Guidance Network (SIGN: 116).

Metabolic control remains at unsatisfactory levels for adolescents in Scotland (Greene & Waugh, 2004). It is therefore important to endeavour to identify some of the psychological factors that may be relevant in predicting, and achieving, better metabolic control in this population.

There has been some evidence to suggest a link between good metabolic control and increased quality of life in an adult diabetes population (Hoey et al., 2001; Varni et al., 2005). Therefore, with what is known about adolescent metabolic control, it is important to examine whether psychological factors, such as attachment, self-esteem and emotional distress also impact upon quality of life in this population.

Following systematic review, there is some evidence that mobile phone interventions may be useful in improving outcomes for adolescents with type 1 diabetes; further research has been recommended.

Therefore, this study aimed to examine the potential impact that psychological factors including attachment, self-esteem and emotional distress, had on the metabolic control and quality of life of adolescents who had type 1 diabetes. The impact of ‘wellbeing text-messaging support’ on metabolic control and quality of life was also investigated.

Based on previous findings and research, the following hypotheses are presented:
2.2 Hypotheses

2.2.1 Hypothesis 1a

Secure attachment will predict better outcome in relation to metabolic control (as measured by HbA1c) and dismissing, fearful and preoccupied attachments will predict poorer metabolic control in an adolescent population with type 1 diabetes

2.2.2 Hypothesis 1b

Secure attachment will predict better quality of life and dismissing, fearful and preoccupied attachments will predict poorer quality of life in an adolescent population with type 1 diabetes

2.2.3 Hypothesis 1c

High levels of emotional distress and low self-esteem will predict poorer outcomes in relation to metabolic control and quality of life in an adolescent population with type 1 diabetes

2.2.4 Hypothesis 2

‘Wellbeing text–messaging support’ will result in improved metabolic control and quality of life in an adolescent population with type 1 diabetes
3 Method

3.1 Design

This study involved a longitudinal, questionnaire design to examine whether the psychological factors attachment, self-esteem, and emotional distress predicted metabolic control (as measured by HbA1c) and quality of life in an adolescent diabetes population. The study went on to evaluate the effectiveness of wellbeing support, sent via an established text-messaging service (Sweet Text), in relation to HbA1c and quality of life. Sweet Text was designed for use with the paediatric diabetes population in Tayside and is used as part of routine clinical practice (Franklin et al., 2006).

The study was approved by the East of Scotland Research Ethics Service (EoSRES) REC1 in January 2012 (appendix 1) and then by the Tayside Medical Science Centre (TASC) Research and Development office (appendix 2).

3.2 Participants

3.2.1 Selection criteria

The target population consisted of all adolescent diabetes patients aged 12-18 years, inclusive, who attend for regular review at diabetes clinics across Tayside. All adolescents who had been diagnosed with Type 1 diabetes mellitus for over one year were invited to participate in the current study. A letter informing the adolescents of the research was sent out prior to their routine appointment. This included a study information sheet with contact details for the chief investigator and an offer to discuss any queries prior to their routine appointment.

3.2.2 Inclusion criteria

- Participants aged 12-18 inclusively who had been diagnosed with Type 1 diabetes mellitus for at least 12 months.
Participants were required to have had a diagnosis of type 1 diabetes for at least one year due to the ‘honeymoon’ phase typically experienced during the first 12 months following diagnosis when the pancreas is still producing small amounts of insulin. Metabolic control is influenced by the potential effects of residual pancreatic activity during this time (Skinner and Hampson, 2001). Therefore, the current study adhered to the recommendation that a 12-month period following diagnosis be kept when researching metabolic control (Shroff Pendley et al., 2002).

3.2.3 Exclusion criteria

- Individuals deemed unable to consent as per the Age of Legal Capacity (Scotland) Act, 1991. This included individuals with an intellectual disability and individuals with global impairment due to head injury.
- Current hypo- or hyperglycaemia (blood glucose below 4mmol/mol or above 20mmol/mol) at the time of assessment.
- Individuals with a diagnosed psychiatric disorder

The young people taking part were required to complete a number of self-report questionnaires independently; therefore capacity to consent was required to ensure the participants fully understood the implications of their participation. Capacity was assessed by the diabetes staff team at the review clinic.

Cognitive functioning rapidly declines when individuals’ blood glucose levels become too high or too low (Strudwick et al., 2005), therefore adolescents who were in a hypoglycaemic (blood glucose below 4mmol: Cryer, 2002) or hyperglycaemic (above 20mmol) state were temporarily excluded from the current study. The participants were allowed to rejoin once their blood glucose levels had stabilised.

Participants were excluded if they met diagnosis for psychiatric disorder in order to reduce potential confounding variables, particularly in relation to metabolic control and response bias when completing the measures. Acute mental health difficulties have been found to be strongly associated with decreased metabolic control (Lawrence et al., 2006; Leonard et al., 2002). In relation to mood and anxiety disorders, evidence would suggest
increased prevalence in an adolescent diabetes population in comparison with adolescents without diabetes (Grey et al., 2002; Dantzer et al., 2003; Kovacs et al., 1989); therefore mood and anxiety, measured as emotional distress, was chosen as a potential predictor of metabolic control and quality of life in the current study.

3.2.4 Sample size

3.2.4.1 Power Analysis

In order to avoid making a Type II error, that is, deciding there is no effect when there is a real effect, a power calculation was conducted prior to recruitment, in order to calculate the sample size required for this investigation. A formal sample size calculation was carried out using Statistics Calculator Versions 3.0 BETA, a statistical package used to calculate sample size (Soper, 2006). In order to detect a medium effect size (0.15), based on a-priori sample size calculation for hierarchical multiple regression, at the significance alpha level of 0.05 and power level of 0.8, for the 6 assessment scales to be statistically analysed as predictors (attachment, as measured by the four subscales of the A-RQ; self esteem, measured by a subscale of the SIP-A; and emotional distress, measured by the PI-ED) and the criterion variables (quality of life, measured by the diabetes-specific PedsQL; and HbA1c), a sample size of 73 was required.

3.3 Sample description

The present sample included 60 participants (37 female and 23 male), aged 12-18 years. There were 89 eligible participants available during the study period. Fourteen (16%) eligible participants refused consent and 15 (17%) did not attend their clinic appointment. Of the remaining 60 participants who did consent to take part, 3 (5%) declined the offer of text-messaging support for the following reasons: they did not own a mobile phone (n=1) and they did not want ‘reminders’ that they have diabetes (n=2). In summary, 60 participants completed the questionnaire component of the study and of those, 57 participants went on to receive ‘wellbeing text-messaging support’ via Sweet Text.
3.4 Procedure

At least one week prior to their routine diabetes review clinic appointment, a letter of invitation (appendix 3a), young person’s information sheet (appendix 3b) and parent/guardian information sheet (appendix 3c) was sent to prospective participants and their parent/guardian inviting them to consider taking part in the study at their next clinic visit. The letter included contact details for the researcher in case there was a need to clarify any information before being approached in clinic. All of the prospective participants who met criteria for inclusion were approached on arrival to the diabetes clinic where it was made clear that declining to take part would not impact upon the care they received in clinic, to eliminate any potential pressure the participants may have felt to take part. Those who elected to take part were asked to provide written consent (appendices 3d and 3e) and the parents of young people under the age of 16 years old were also asked to provide written consent, which was consistent with the study ethical agreement. Those who declined to participate in the study received care as usual for their diabetes and were thanked for their consideration.

All participants were required to undertake the same assessment procedure. Questionnaire packs were distributed and completed during routine clinics, where participants often have to wait for consultation with several members of the diabetes staff team. The packs were completed in the waiting areas of the clinics. Typically, a parent or guardian accompanied the young people to their review therefore emphasis was placed on the participants’ completing the measures without assistance to avoid any bias in socially desirable responses. It was recommended that the participants sit in a different part of the waiting area to complete the measures independently.

Participants were asked to complete four questionnaires including measures of attachment security (A-RQ), emotional distress (PI-ED), self esteem (SIP-A) and diabetes-related quality of life (PedsQL), to be described in detail in the following section. Demographic information was also collected and this included age, gender, length of diagnosis, method of insulin delivery (injection or pump), and location of diabetes clinic (appendix 4). Participants were also asked whether or not they had a diagnosis of a psychiatric disorder since this would have excluded them from taking part in the study. In order to maintain
participant confidentiality, this question was included in the demographic information section at the start of the anonymised questionnaire pack.

On completion of the questionnaire pack, the participants were asked to provide their mobile phone number in order for them to be commenced onto the wellbeing module of Sweet Text within the week following their clinic appointment. None of the participants had previously received the wellbeing module. They were reminded the module consisted of one text per day across a three week period as per routine practice. Participants were also informed that a follow-up questionnaire pack, comprising two questionnaires (PedsQL and an evaluative questionnaire, designed to measure satisfaction with the wellbeing module) would be posted to their home address following completion of the wellbeing module together with a stamped envelope addressed to the chief investigator for their return.

Participants were commenced onto the wellbeing module, typically to begin the day after clinic attendance. There were exceptions to this such as when a young person was already using Sweet Text to receive a different module. In the event of this situation, which occurred on two occasions, the participant was commenced onto the wellbeing module as soon as possible following the completion of the previous module.

HbA1c values were collected on two occasions from the clinical notes, including at the time of the initial and subsequent clinic appointments. This was designed to provide a measure of metabolic control before and after the participant received text-messaging support.

All of the study documentation, including consent forms and anonymised questionnaire packs, were stored in a locked filing cabinet, located in a locked room at a local NHS site. No identifying information was included on the study database. The researcher’s contact details were highlighted in the event of questions following participation and all participants were given the option of requesting a summary of the study findings.
3.5 Measures

All measures used within the study were standardised, reliable and valid, and designed or adapted for use with an adolescent population (Ravitz et al., 2010, Butler & Gasson, 2005, O’Connor et al. 2010, Varni et al., 2003, Scharfe, 2009). The measures used are summarised in Table 3.

Table 3: Summary of assessment measures

<table>
<thead>
<tr>
<th>Area assessed</th>
<th>Measure of assessment</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attachment security</td>
<td>The Adolescent Relationship Questionnaire (A-RQ)</td>
<td>Bartholomew &amp; Horowitz (RQ; 1991); adapted for adolescents by Scharfe (A-RQ; 2009)</td>
</tr>
<tr>
<td>Diabetes-specific Quality of Life</td>
<td>Pediatric Quality of Life Inventory (PedsQL – Diabetes Module 3.0)</td>
<td>Varni et al. (2003)</td>
</tr>
<tr>
<td>Emotional Distress</td>
<td>Paediatric Index of Emotional Distress (PI-ED)</td>
<td>O’Connor et al. (2010)</td>
</tr>
<tr>
<td>Self esteem</td>
<td>Self Image Profile for Adolescents (SIP-A)</td>
<td>Butler et al. (2001)</td>
</tr>
</tbody>
</table>

3.5.1 Counterbalancing

The questionnaire measures were presented using a counterbalanced design to reduce the chances of the order of treatment, or other factors such as fatigue, adversely influencing the results. Due to the number of measures and the known complexities of complete counterbalancing in a multi-condition design, a balanced Latin Square approach (Bradley, 1958) informed the counterbalancing process. Ten orders of presentation were repeated throughout the counterbalancing procedure.
3.5.2 Attachment

The A-RQ attachment measure was used in a study of similar design (Henderson, 2010 unpublished dissertation) and will be replicated in the current study to provide a dominant attachment style category in addition to a continuous measure of attachment security. The Adolescent Relationship Questionnaire (A-RQ: Scharfe, 2009) is a version of the Relationship Questionnaire (RQ: Bartholomew & Horowitz, 1991), adapted for use by an adolescent population and is freely available online. The 4-item questionnaire measures ‘secure’, ‘fearful’, ‘preoccupied’ and ‘dismissing’ attachment styles in terms of the degree to which each style applies to the individual, using a standard Likert scale (range 1-7, where 1 means ‘not at all like me’ and 7 means ‘very much like me’). The A-RQ also provides what the individual perceives is their dominant attachment style. The RQ has been used effectively in many studies that include young adults and adolescents (Broberg et al., 2001; Matsuoka et al., 2006; Scharfe & Eldredge, 2001) and was considered to have strong psychometric properties in a recent 25-year review of attachment measures (Ravitz et al., 2010).

3.5.3 Self Esteem

The Self Image Profile for Adolescents (SIP-A; Butler, 2001) is a self report measure designed for adolescents aged 12-16 years old. The 25 item Likert scale questionnaire (range 0-6 where 0 means ‘not at all’ and 6 means ‘very much’ like the description) includes 12 ‘positive’ items, 12 ‘negative’ items and 1 ‘neutral’ item. Through two ratings, it provides a positive and negative measure of self image (e.g. how I think I am), a measure of self difference (estimated by the adolescents as how alike they feel in comparison with others) and self esteem (SE), which is estimated by the discrepancy between ratings of ‘how I think I am’ and ‘how I would like to be’. A high SE score, particularly above the recommended cut-off scores provided for each age and gender, reflects a wide discrepancy and is therefore indicative of low self esteem. According to recent literature, there is some evidence to suggest a relationship between self esteem and diabetes in an adolescent population (de Sá Navato et al., 2007), therefore the self esteem subscale was utilised for the current study. The measure was highlighted in a recent review as a reliable and valid measure of self esteem and the only scale to have been developed and published with British norms (Butler & Gasson, 2005).
3.5.4 Emotional Distress

The Paediatric Index of Emotional Distress (PI-ED: O’Connor et al., 2010) is a paediatric measure of emotional distress based on the Hospital Anxiety and Depression Scale (HADS: Zigmond & Snaith, 1983). This 14 item questionnaire was developed to provide a single measure of emotional distress for a paediatric population and has been standardised on children and young people aged 8-16 years old. Participants score each item based on how they have been feeling over the last week. The PI-ED is scored in accordance with the test manual: each item is allocated a score from 0 to 3 (some items are scored in reverse) which are added together to reach a total score. If a score is at or above the gender-specific cut-off values provided, they are deemed likely to be experiencing clinically significant levels of distress. The PI-ED offers a valid, reliable and brief measure of emotional distress in children and young people. This measure is used clinically in diabetes clinics across Tayside as part of standard routine care.

3.5.5 Quality of Life

Health-rated quality of life measurement has emerged as an important health outcome in clinical trials (Varni et al, 2005). Perhaps as a reflection of this, research involving the adolescent diabetes population has started to evaluate quality of life (Grey et al, 1998; Pereira et al., 2009). In relation to the measurement of quality of life, evidence has suggested that diabetes-specific scales are more sensitive to change in diabetes populations (Jacobson et al. 1994; Polonsky, 2000), therefore the current study has utilised the Paediatric Quality of Life Inventory (PedsQL – 3.0 diabetes module: Varni et al., 2003) that uses diabetes-specific items to assess quality of life in this adolescent population.

The PedsQL is a 28 item Likert scale questionnaire for 13-18 year olds with Type 1 diabetes that identifies 5 scales: diabetes symptoms, treatment barriers, treatment adherence, worry and communication. Participants score each item depending on how frequently the item has been a problem for them over the last month (ranging from 0 indicating ‘never’ to 4 indicating ‘almost always’).
The measure was scored according to the test manual. Items are reverse scored and linearly transformed to a 0 to 100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0. To achieve total score, for each individual scale and an overall total, all of the items are summed and averaged, with higher scores indicating fewer symptoms or problems. This is supported as a reliable and valid measure of quality of life in an adolescent diabetes population based upon a sample size of 147 adolescents (Varni et al., 2003; Varni et al. 2005) with Cronbach’s alpha of .77 (Varni et al., 2003).

3.5.6 Metabolic control

HbA1c is a measure of blood glucose variation over the previous four to twelve weeks (Rewers et al., 2007). Blood tests taken on the day of the clinic by the diabetes nursing staff were obtained from participants’ clinical notes within the week following initial and subsequent clinic appointments. HbA1c monitoring is the most useful measure in evaluating metabolic control and has been shown to accurately predict later microvascular and macrovascular complications (Rewers et al., 2007; Diabetes Control and Complications Trial, DCCT, 1993). Since June 2011, the way HbA1c values are reported has switched from a percentage to a measurement in mmol/mol (International Federation of Clinical Chemistry: IFCC) units in order to standardise results worldwide. Optimal metabolic control is identified as <58 mmol/mol units (International Federation of Clinical Chemistry: IFCC).

3.6 Ethical considerations

3.6.1 Participant confidentiality

In order to ensure participant anonymity and confidentiality, questionnaire packs and HbA1c values were each assigned a study number for identification purposes. The data were collected between February and June 2012. All of the project documentation, including questionnaire packs, consent forms and the list of identification numbers, was stored securely in locked filing cabinets on NHS property, and remain the responsibility of the Chief Investigator. The data will be kept securely for a period of five years in accordance with research guidelines and ethical approval.
3.6.2 Participant distress

It was not expected that participants would become distressed as a result of taking part in the current study. The study measures are standardised and used routinely in clinical practice and research with adolescent, paediatric and/or diabetes populations with no reported evidence of adverse or detrimental effects. Additionally, where possible, the adolescent versions of the measures have been used to avoid additional completion time and possible distress as a result of fatigue. The Sweet Text system is used as part of normal clinical practice within NHS Tayside with no reported detrimental effects (Franklin et al., 2006).

Participants were attending the clinic(s) for their regular and routine review of their diabetes within the managed clinical network of the Diabnet diabetes service. As such, they remained under the medical and psychological care of the diabetes team throughout the study period. If participants had become distressed during participation, the chief investigator would have informed the diabetes team since onsite clinical psychology and care management were already in place.

The use of the PI-ED measure led to the possibility that clinically significant emotional distress may be detected in the study population. If any participant scored above the ‘cut-off’ it was agreed that the chief investigator would discuss with the young person whether or not to share this information with the diabetes team, considering the participant’s right to confidentiality as well as duty of care.

3.7 Method of Analyses

Analysis of the data was conducted using a range of statistical procedures via the Statistical Package for the Social Sciences (SPSS: for Windows, version 19.0, SPSS Inc., Chicago). Exploratory data analysis methods were used to ascertain whether the data met the assumptions of parametric statistical methods. The assessment of the normality of distributions was particularly important because many inferential statistics are not robust to violations of this assumption (Tabachnick & Fidell, 2001). Therefore box plots and histograms were examined and the Kolmogorov-Smirnov test was conducted to assess normality.
The study hypotheses were evaluated by means of hierarchical regression analysis, carried out to examine the relationships between the predictor variables (attachment, self esteem and emotional distress) and the criterion variables (metabolic control and quality of life). Pearson correlation coefficient was carried out to examine the links between participant scores and t-tests were used to evaluate the effectiveness of ‘wellbeing text-messaging support’ in relation to HbA1c and quality of life. Effect size calculations were performed using G*Power.
4 Results

4.1 Participant characteristics

4.1.1 Demographic characteristics

Demographic data are summarised in Table 4. In the total sample, 37 (62%) participants were female and 23 (38%) were male. The participants’ average age was 15 years with an average length of diagnosis of 7 years. Of the 60 participants, 48 (80%) were seen at the Dundee clinic with the remaining participants seen at satellite clinics across Tayside.

Table 4: The demographic characteristics of the study sample, including average age and length of diagnosis

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years</td>
<td>15.23 (1.70)</td>
<td>12 – 18</td>
</tr>
<tr>
<td>Length of diagnosis</td>
<td>7.02 (3.99)</td>
<td>1 – 15</td>
</tr>
</tbody>
</table>

N=60

4.1.2 Clinical Characteristics

In the current sample, 44 of the 60 participants (73.3%) used injections to deliver their insulin treatment; the remaining 16 (26.7%) used an insulin pump. The average HbA1c for the study sample was 77.52 mmol/mol (SD=19.95) (range 41-125). The recommended optimal value for HbA1c is <58mmol/mol (IFCC), therefore the average HbA1c in the current sample is higher than recommended indicating poor metabolic control. More specifically, 7 (11.6%) participants (5 male and 2 female) met the recommendations for optimal HbA1c; therefore, the majority of the study sample (n=53: 88.4%) were categorised as having poor metabolic control.
4.1.3 Attachment style

The percentage of sample participants classified as each attachment style, as defined by the self-report measure A-RQ, is tabulated below (see Table 5). Forty (66.7%) participants identified secure attachment as their dominant attachment style. Seven (11.7%) participants described their dominant attachment style as fearful. Five (8.3%) participants identified their predominant attachment style as preoccupied and eight (13.3%) identified with a predominant dismissing attachment style. In summary, the majority of the participants in the study sample classified themselves as securely attached and the smallest number of participants classified their predominant attachment style as preoccupied.

Table 5: The attachment style classifications of the study sample

<table>
<thead>
<tr>
<th>Attachment style</th>
<th>Number of participants (% of sample)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secure</td>
<td>40 (66.7)</td>
</tr>
<tr>
<td>Fearful</td>
<td>7 (11.7)</td>
</tr>
<tr>
<td>Preoccupied</td>
<td>5 (8.3)</td>
</tr>
<tr>
<td>Dismissing</td>
<td>8 (13.3)</td>
</tr>
</tbody>
</table>

The A-RQ provides both a category and a continuous measure of attachment style; for the purposes of analysis, the continuous measure of attachment was used.

4.2 Correlations

To examine the relationships between the variables, Pearson’s correlation coefficients were calculated (Table 6).

4.2.1 HbA1c

HbA1c was found to be negatively correlated with secure attachment ($r = -.41, p<.001$) and quality of life ($r = -.48, p<0.001$) and positively correlated with fearful attachment ($r = .46, p<.001$) and emotional distress ($r = .37, p<.01$).

Lower HbA1c (indicating better metabolic control) was associated with higher levels of secure attachment and better diabetes-related quality of life (higher scores on the
PedsQL) and higher HbA1c values (indicating worse metabolic control) was associated with higher levels of fearful attachment and higher levels of emotional distress.

4.2.2 Quality of Life
Quality of life (as measured by the PedsQL) was found to be positively correlated with secure attachment (r = .60, p<.001) and negatively correlated with fearful (r = -.59, p<.001) and preoccupied (r = -.45, p<.001) attachments, self esteem (r = -.51, p<.001) and emotional distress (r = -.70, p<.001).

Better quality of life (higher scores on the PedsQL) was associated with higher levels of secure attachment. Poorer quality of life (lower scores on the PedsQL) was associated with higher levels of fearful and preoccupied attachments, poorer self esteem (higher scores using the SIP-A measure) and high levels of emotional distress (higher scores using the PI-ED).

The relationships between the predictor variables were as follows. Secure attachment was negatively correlated with emotional distress (r = -.69, p<.001) and self esteem (r = -.32, p=.007); fearful attachment was positively correlated with emotional distress (r = .59, p<.001) and self esteem (r = .38, p=.001); preoccupied attachment was also positively correlated with emotional distress (r = .38, p=.001) and self esteem (r = .29, p=.012); and emotional distress was found to have a positive correlation with self esteem (r = .55, p<.001).

There was an association found between higher levels of secure attachment and less emotional distress (lower scores on the PI-ED) as well as higher self esteem (lower SIP-A scores). There was also an association found between higher levels of fearful attachment and higher emotional distress (higher PI-ED scores) as well as poorer self esteem (higher SIP-A scores). Higher levels of preoccupied attachment were associated with increased emotional distress and lower self esteem. The positive correlation between emotional distress and self esteem would suggest an association between lower self esteem (high scores on the SIP-A) and higher emotional distress (high PI-ED scores).
As expected, higher levels of secure attachment was negatively correlated with higher levels of fearful ($r = -.60$, $p<0.001$) and preoccupied ($r = -.491$, $p<0.001$) attachment styles; and higher levels of fearful attachment was positively correlated with higher levels of preoccupied attachment ($r = .364$, $p=0.003$). Dismissing attachment approached a negative correlation with secure attachment ($r = -.214$, $p=.054$).
Table 6: Pearson correlations (r) for measures of attachment, self esteem, emotional distress, metabolic control and diabetes-related quality of life

<table>
<thead>
<tr>
<th>Age</th>
<th>A-RQ secure attachment</th>
<th>A-RQ fearful attachment</th>
<th>A-RQ preoccupied attachment</th>
<th>A-RQ dismissing attachment</th>
<th>SIP-A self esteem</th>
<th>PI-ED emotional distress</th>
<th>Metabolic control (HbA1c)</th>
<th>PedsQL quality of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Pearson's (r)</td>
<td>Sig. (p)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-RQ secure attachment</td>
<td>R</td>
<td>-.046</td>
<td>.366</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-RQ fearful attachment</td>
<td>R</td>
<td>.107</td>
<td>.212</td>
<td>-.595***</td>
<td>&lt;.001</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-RQ preoccupied attachment</td>
<td>R</td>
<td>-.094</td>
<td>.242</td>
<td>-.491***</td>
<td>&lt;.001</td>
<td>.364**</td>
<td>.003</td>
<td>1</td>
</tr>
<tr>
<td>A-RQ dismissing attachment</td>
<td>R</td>
<td>.158</td>
<td>.118</td>
<td>-.214</td>
<td>.054</td>
<td>-.069</td>
<td>.304</td>
<td>.032</td>
</tr>
<tr>
<td>SIP-A self esteem</td>
<td>R</td>
<td>-.044</td>
<td>.372</td>
<td>-.323**</td>
<td>.007</td>
<td>.384***</td>
<td>.001</td>
<td>.294*</td>
</tr>
<tr>
<td>PI-ED emotional distress</td>
<td>R</td>
<td>.069</td>
<td>.303</td>
<td>-.677***</td>
<td>&lt;.0001</td>
<td>.586***</td>
<td>&lt;.001</td>
<td>.384***</td>
</tr>
<tr>
<td>Metabolic control (HbA1c)</td>
<td>R</td>
<td>.006</td>
<td>.482</td>
<td>-.410***</td>
<td>&lt;.001</td>
<td>.465***</td>
<td>&lt;.001</td>
<td>.128</td>
</tr>
<tr>
<td>PedsQL quality of life</td>
<td>R</td>
<td>.045</td>
<td>.368</td>
<td>.602***</td>
<td>&lt;.001</td>
<td>-.590***</td>
<td>&lt;.001</td>
<td>-.447***</td>
</tr>
</tbody>
</table>

*p<0.05; **p<0.01; ***p<0.001
4.3 Exploratory Analysis and Data Cleaning

Psychometric information for the self-report measures is summarised in Table 7. Each of the study measures was found to have good internal consistency indicating that they may be used reliably within the present study. The PI-ED (emotional distress) had a Cronbach alpha of .84; the SIP-A (self esteem) had a Cronbach alpha of .90; and the PedsQL (diabetes-specific quality of life) scale had a Cronbach alpha coefficient of .90.

Table 7: Reliability coefficients, mean values and standard deviations of the measures used in the current study (PI-ED, SIP-A and PedsQL).

<table>
<thead>
<tr>
<th>Measure</th>
<th>Cronbach’s α</th>
<th>Mean (s.d.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI-ED (emotional distress)</td>
<td>.84</td>
<td>12.60 (5.46)</td>
</tr>
<tr>
<td>SIP-A (self esteem)</td>
<td>.90</td>
<td>39 (18.98)</td>
</tr>
<tr>
<td>PedsQL (Quality of Life)Total</td>
<td>.90</td>
<td>66.53 (14.27)</td>
</tr>
</tbody>
</table>

4.3.1 Missing Data

Determining the extent and pattern of missing data is of interest as these factors may affect outcomes and interpretations of data (Fox-Wasylyshyn & El-Masri, 2005). Missing Values Analysis (SPSS, version 19.0) showed that no pre-intervention variables had more than 5% missing data therefore no transformations were indicated and no further analysis undertaken. It is noteworthy, however that the statistical package used reduced the number of complete data sets analysed by two (n=58). This was as a result of two full measures that were not completed.

Exploratory data analysis was undertaken via examination of descriptive frequency data and box plots. A few univariate outliers were identified, however as these were considered to be true values representative of the full range of the measures used they were retained. No multivariate outliers were identified; therefore parametric statistics could be performed without the need for transformation of the data.
It is important to assess the normality of the distribution of the variables examined as normality is a core assumption of many statistical tests, and many inferential statistics are not robust to violations of this assumption (Tabachnick & Fidell, 2001). In the present research, the skewness and kurtosis of the distributions were assessed through SPSS explore, examination of histograms and examination normality probability plots. None of the variables were found to exhibit kurtosis or significantly skewed variables.

Examination of the scatterplots of standardised residuals against standardised predicted scores (for each regression conducted) showed no obvious pattern (such as a crescent- or funnel-shaped cloud of points), and so we can conclude that the assumptions of linearity and homogeneity of variance were met (appendix 11). In the examination of collinearity no problems with the intercorrelation of variables was identified.

**4.4 Hypotheses testing**

**Hypothesis 1a**
Secure attachment will predict better outcome in relation to metabolic control (as measured by HbA1c) and dismissing, fearful and preoccupied attachments will predict poorer metabolic control in an adolescent population with type 1 diabetes

**Hypothesis 1b**
Secure attachment will predict better quality of life and dismissing, fearful and preoccupied attachments will predict poorer quality of life in an adolescent population with type 1 diabetes

**Hypothesis 1c**
High levels of emotional distress and low self-esteem will predict poorer outcomes in relation to metabolic control and quality of life

To determine whether HbA1c and Quality of Life could be predicted on the basis of attachment security, emotional distress and self esteem, two hierarchical regressions (one for each criterion variable) were conducted. One demographic variable (age) was entered
using the ‘enter’ method in the first step of the regression analysis and the remaining variables including secure, fearful, preoccupied and dismissing attachment styles (A-RQ), emotional distress (PI-ED) and self esteem (SIP-A) were added during the second step using the ‘stepwise’ method (Brace et al. 2003). See Table 8 for the results of the analysis.

### Table 8: Hierarchical regression analysis outcome for HbA1c and quality of life

<table>
<thead>
<tr>
<th></th>
<th>β</th>
<th>R</th>
<th>R²</th>
<th>Adjusted R²</th>
<th>Standard Error</th>
<th>F-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HbA1c</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Age</td>
<td>-.440</td>
<td>.006</td>
<td>.000</td>
<td>-.018</td>
<td>20.35</td>
<td>0.002</td>
</tr>
<tr>
<td>2. Fearful attachment</td>
<td>.470</td>
<td>.467</td>
<td>.218</td>
<td>.190</td>
<td>18.16</td>
<td>7.66*</td>
</tr>
<tr>
<td><strong>Quality of Life</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Age</td>
<td>.113</td>
<td>.450</td>
<td>.002</td>
<td>-.016</td>
<td>14.38</td>
<td>0.11</td>
</tr>
<tr>
<td>2. Emotional distress</td>
<td>-.539</td>
<td>.705</td>
<td>.498</td>
<td>.479</td>
<td>10.29</td>
<td>27.23*</td>
</tr>
<tr>
<td>3. Fearful attachment</td>
<td>-.287</td>
<td>.742</td>
<td>.551</td>
<td>.526</td>
<td>9.82</td>
<td>22.10*</td>
</tr>
</tbody>
</table>

*p<0.001, n=58

### 4.4.1 HbA1c

In relation to HbA1c, regression analysis showed that the variables that entered the regression equation accounted for 19% of the variance in HbA1c (adjusted R square = .190; F 2,55 = 7.66, p<0.001, using the stepwise method). More specifically, the demographic variable age accounted for 1.8% of the variance and fearful attachment, as measured by the A-RQ, accounted for a further 17.2% of the variance.

The size and direction of the relationships suggest participants who reported high levels of fearful attachment had poorer metabolic control (higher HbA1c levels). Self esteem, emotional distress and the remaining attachment styles (secure, preoccupied and dismissing) did not appear to have significant impact on HbA1c therefore did not predict outcome.
In relation to the HbA1c regression model, effect size calculations, Cohen’s $f^2 = \frac{R^2}{1 - R^2}$ revealed a large effect size of 0.28 and power $(1 - \beta)$ of 0.79, which indicates that the analysis was sufficiently powered (Soper, 2006).

4.4.2 Quality of Life

In relation to quality of life, regression analysis demonstrated that the variables that entered the regression equation accounted for 52.6% of the variance in quality of life (adjusted $R$ square = .526; $F_{3,54} = 22.11$, $p<0.001$, using the stepwise method). The demographic variable age accounted for 1.6% of the variance, and the psychological factors emotional distress (as measured by the PI-ED) accounted for a further 46.3%, and fearful attachment (as measured by the A-RQ) accounted for the remaining 4.7% of the variance.

The size and direction of the relationships suggest participants who have high levels of fearful attachment and higher levels of emotional distress will have poorer quality of life (as indicated by a lower score on PedsQL). Self esteem and the remaining attachment styles (secure, preoccupied and dismissing) were not significant predictors in this model.

In relation to the quality of life regression model, effect size calculations, Cohen’s $f^2 = \frac{R^2}{1 - R^2}$ revealed a very large effect size of 1.22 and power $(1 - \beta)$ of 0.99, which indicates that the analysis was sufficiently powered (Soper, 2006).

Hypothesis 2

‘Wellbeing text–messaging support’ will result in improved metabolic control and quality of life in an adolescent population with type 1 diabetes

A paired samples t-test was conducted to compare the HbA1c values (n=21) and quality of life scores (n=16) before and after participants received ‘wellbeing text-messaging support’ via the Sweet Text system (see Table 9). In relation to metabolic control, the difference was approaching significance in HbA1c values ($t=1.703$, $df=20$, $p=.052$, one-tailed). The magnitude of the difference in the means ($d=0.16$) indicated a small effect
size. A significant difference was detected in quality of life scores (t=1.938, df=15, p=.036, one-tailed). The magnitude of the difference in the means (d=0.31) indicated a small to moderate effect size.

Table 9: Means, standard deviations and range of HbA1c and Quality of Life (as measured by the PedsQL) pre- and post-text messaging modular support

<table>
<thead>
<tr>
<th>Pre Outcome measure</th>
<th>Mean (SD)</th>
<th>Range</th>
<th>Post Outcome measure</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>*HbA1c</td>
<td>80.86 (19.35)</td>
<td>50 - 113</td>
<td>HbA1c</td>
<td>84.24 (21.58)</td>
<td>48 - 130</td>
</tr>
<tr>
<td>**Quality of Life</td>
<td>62 (16.29)</td>
<td>23.21 - 91.96</td>
<td>Quality of Life</td>
<td>66.52 (13)</td>
<td>47.32 - 90.18</td>
</tr>
</tbody>
</table>

*HbA1c n=21 (35%); **quality of life n=16 (26.7%)

‘Wellbeing text-messaging support’ was found to significantly improve quality of life and a trend towards poorer HbA1c was indicated in an adolescent population with type 1 diabetes.

4.5 Evaluative analysis

There were 15 evaluative questionnaires completed. Of those, 12 (80%) did not want to receive any further wellbeing text messages. Ten (66.7%) received the full three week wellbeing module and five (33.3%) reported that on receiving their first text, it was not clear that the text-messages were from Sweet Text.

In response to how the wellbeing module was ‘helpful’, positive feedback included *I felt reassured* and *it was like someone cares*. Negative feedback stated *it was not overly helpful*.

In response to how the module was ‘annoying’, feedback included *I got the same text more than once* and *I know that stuff already*. Almost half of the participants (46.6%) found the messages *annoying*. 

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Suggestions for improvements in relation to text frequency were mixed, with some participants requesting fewer and others requesting additional messages, and a request for more practical information was identified by two participants.
5 Discussion

5.1 Discussion of descriptive statistics with reference to the literature

5.1.1 HbA1c

The average HbA1c level for the current study was 77.52mmol/mol. As reported, the recommended levels for HbA1c are below 58mmol/mol (National Collaborating Centre for Women’s and Children’s Health, 2004, NICE Guidance, 2004, Rewers et al., 2007). The current study suggests that overall, blood glucose control in the type 1 diabetes adolescent population in Tayside is poor; however, it is consistent with reported HbA1c levels in children and adolescents across the UK (Greene & Waugh, 2004). Further, although the majority of the study participants (88.4%) did not fall within the healthy range of HbA1c, the percentage that did are higher than the average previously reported (Greene & Waugh, 2004), though the reasons for this are not clear.

With reference to the literature, it has been widely reported that metabolic control decreases significantly during the adolescent period (Borus & Laffel, 2010; de Wit et al., 2007; Greene & Waugh, 2004). In one of the few studies in which attachment was measured in an adolescent diabetes population, the study sample was reported as having ‘good’ metabolic control (7.6%, converted for ease of comparison to 60 mmol/mol: International Federation of Clinical Chemistry (IFCC) units). This may be considered unusual given the volume of literature that is indicative of poor metabolic control in this population; that particular study sample may not be representative of the adolescent diabetes population, in which case some caution should be extended when considering their results (Rosenberg & Shield, 2009).

5.1.2 Attachment

In the current study sample, 66.7% (two thirds) identified with a secure attachment style, 11.7% were categorised as fearful, 8.3% as preoccupied and 13.3% as dismissing. In the only other attachment study with an adolescent diabetes population in which the A-RQ was used, over 75% of participants classified themselves as securely attached
(Henderson, 2010, unpublished dissertation). Rosenberg & Shields (2009) used a different measure of attachment that did not categorise attachment styles, which made a comparison with this study unfeasible. On average, in the general population, secure attachment is 55% (Mickelson et al., 1997); thus, in the current study sample, there is an over representation of secure attachment style, which adds some support to Henderson’s findings (2010).

In the context of literature in which the RQ measure of attachment has been used, in a non clinical sample of young adults (aged 17 to 24 years), 57% were classified as secure by Bartholomew and Horowitz (1991) and the percentage of participants classified as dismissing was 18%, preoccupied 10% and fearful 15%. The attachment styles demonstrated by this study sample showed similar patterns to the current study in that the majority of the participants were classified as secure and the smallest number were classified as preoccupied. Another study used the RQ and found 47% of students were categorised as securely attached (Horowitz, 1996). In adolescents aged 17 to 19 years old, using a different measure of attachment, 30% were classified as securely attached (Hamilton, 2000) and when a clinical population of young men was considered, the figure for secure attachment fell to 33% (Troisi et al., 2001). In summary, the current sample appeared to involve a higher percentage of individuals with a secure attachment style in comparison with earlier literature.

Considering the relationship between attachment style, diabetes and the role of psychological factors, in adults with Type 1 and Type 2 diabetes and depression, 29% were classified as secure (Ciechanowski, Russo, Katon, Von Korff et al., 2006) and in a second study with a similar population who did not have depression, higher levels of secure attachment (37.5%) were indicated (Ciechanowski, Hirsch et al., 2002). This suggested that psychological factors significantly impacted attachment classifications in adults with diabetes; therefore it may be important to consider the potential impact of psychological factors when examining attachment security in adolescent diabetes populations.
5.2 Hypotheses testing

The current study examined the nature and impact of attachment security and other psychological factors on the metabolic control and the quality of life of adolescents with type 1 diabetes across Tayside. The effectiveness of ‘wellbeing text-messaging support’ on metabolic control and quality of life with the same population was also examined. The findings suggested that aspects of attachment security had a significant impact on metabolic control and quality of life and emotional distress also significantly impacted upon quality of life. ‘Wellbeing text-messaging support’ was found to significantly impact upon quality of life and a trend was noted towards impact on metabolic control.

This section will summarise the results of the study in relation to each hypothesis and discuss clinical implications, methodological issues and suggestions for future research.

5.2.1 Hypothesis 1a

Secure attachment will predict better metabolic control (as measured by HbA1c) and dismissing, fearful and preoccupied attachment styles will predict poorer metabolic control in an adolescent population with type 1 diabetes

Partial support was found for hypothesis 1a, in that a high level of fearful attachment style was found to significantly predict poorer metabolic control. Thus, the current study found some additional evidence for a relationship between attachment security and metabolic control (HbA1c) in an adolescent diabetes population (Henderson, 2010; Rosenberg & Shields, 2009). The current study also provided some support for the adult diabetes literature where there is a body of evidence to suggest a relationship between attachment and HbA1c (Ciechanowski et al., 2002; Ciechanowski et al., 2004).

Despite providing some support for the adult diabetes literature, the findings of the current study differed from the adult research in an important way. For example, Ciechanowski and colleagues focused on the difference between dismissing and secure attachment styles and argued that individuals with a dismissing attachment style were more at risk of poor metabolic control than those with a secure attachment (Ciechanowski
et al., 2002). The authors explained that individuals with a dismissing attachment style hold a negative view of others and a positive view of self. This, they suggested, was as a result of consistently, emotionally unresponsive early care giving, leading to a tendency towards self-reliance and less trust of others. In terms of health care, this may result in missed appointments and poorer collaboration with health care providers which may in turn adversely affect diabetes self-management, potentially impacting upon metabolic control. If the important link underlying attachment and its relationship with metabolic control is the negative view of others, as identified as a characteristic of dismissing attachment style, it is therefore important to consider that this is a shared characteristic between fearful and dismissing attachment styles. Dismissing and fearful attachment styles are said to have a shared tendency to find social interactions unrewarding and a belief that others are unavailable and/or incapable of care and so they avoid forming relationships with others. If this is so, both attachment styles may present in a similar way to health care staff, for example as if they are invulnerable or not in need of care and with a tendency to avoid elaborating on any worsening symptoms, since they may want to avoid eliciting support from others. The same individuals may also not seek support from family members which is particularly important in diabetes care since diabetes treatment is mainly the responsibility of the family and parents in childhood and early adolescence (Leonard et al., 2005). It may also be important to note that one third of the adult subjects in the aforementioned study were classified as dismissing which was considerably higher than the current study at 13.3% and indeed higher than average (25%) (Ciechanowski et al., 2002). This may have impacted somewhat on the study findings.

As reported, in the current study sample, fearful attachment style predicted poorer metabolic control. Individuals with a fearful attachment style are hypothesised to have had rejecting-style care-giving leading to the likelihood of approach-avoidance interpersonal behaviour (Ciechanowski et al., 2004). As previously discussed, individuals with a fearful attachment style tend to have a negative view of others; however, in contrast with a dismissing attachment style, individuals who are fearful are also thought to have a negative view of self. In health care, this negative self view may manifest itself as an inability to demonstrate or prioritise self-care, which is, of course, an integral aspect of diabetes management. Thus, it may be hypothesised that in addition to failing to seek support from others, individuals with a fearful attachment style may find it difficult to
prioritise self-care, the combination of which is likely to impact on the self-management of a complex, chronic illness like type 1 diabetes.

In summary, the current study demonstrated a direct relationship between fearful attachment security and poorer HbA1c in an adolescent diabetes population. This may have occurred as a result of the combination of the characteristic negative view of self and others associated with a fearful attachment style. It has been hypothesised that a fearful attachment style may lead to difficulties in individuals prioritising self care as well as the inability to expect or seek care from others, such as family members and/or health care providers that may result in poorer management of type 1 diabetes and ultimately poorer metabolic control.

5.2.2 Hypothesis 1b

Secure attachment will predict better quality of life, and dismissing, fearful and preoccupied attachments will predict poorer quality of life in an adolescent population with type 1 diabetes

Partial support was found for hypothesis 1b. Fearful attachment style significantly predicted poorer quality of life in an adolescent diabetes population. The current study is the only one to consider the impact that attachment security may have on the quality of life of an adolescent diabetes population.

As previously discussed, individuals who have a fearful attachment style are hypothesised to have a negative view of self and others that may manifest itself in an inability to prioritise self-care as well as a failure to expect to or seek support from others. Type 1 diabetes requires intensive daily self-management tasks, such as managing blood glucose and insulin administration and, in early adolescence, as previously discussed, diabetes care is mainly the responsibility of parents and family (Leonard et al., 2005). Therefore, even with support, adolescents with diabetes may face many challenges on a daily basis that can interfere with ‘normal’ relationships and activities and therefore potentially quality of life. In the context of fearful attachment, coping with the intensive self-management required daily for diabetes without support or indeed comfort, either from self or others, may act as an obstacle in relation to facilitating optimal quality of life.
As previously reported, health-related quality of life measurement has emerged as an important health outcome in clinical trials, clinical practice improvement strategies and healthcare service research and evaluation (Varni et al., 2005). As discussed, individuals with fearful attachments may be less likely to seek support for diabetes management which may in turn impact negatively on metabolic control. Linking with recent evidence, good metabolic control has been associated with better quality of life (Hoey et al., 2001; Varni et al., 2005), therefore, not seeking support may also result in poorer quality of life in diabetes populations. In health care, current guidelines emphasise the potential impact that diabetes can have on an individual’s quality of life, highlighting its importance and the need for further research regarding identifying some of the psychological factors that may impact quality of life in this population.

In summary, the current study demonstrated a direct relationship between fearful attachment security and poorer quality of life in an adolescent diabetes population. It has been hypothesized that this may be due to the combination of the negative view of self and others found in individuals with fearful attachment. Adolescents who are fearful may be less likely to seek support towards diabetes management or to elaborate on worsening symptoms; this would likely impact upon whether or not they received appropriate treatment or advice towards the improvement of quality of life.

5.2.3 Hypothesis 1c

*High levels of emotional distress and low self-esteem will predict poorer outcomes in relation to metabolic control and quality of life*

Hypothesis 1c was partially supported by the current study. Emotional distress significantly impacted on quality of life in an adolescent diabetes population. No significant effect of self esteem was found.

Current literature would suggest increased prevalence of psychological difficulties, such as depression, anxiety and lower self esteem, in an adolescent diabetes population when compared with adolescents without diabetes (Grey et al., 2002; Dantzer et al., 2003; Kovacs et al., 1989). This evidence is somewhat reflected in the current care guidelines
where access to mental health professionals is recommended for individuals with diabetes due to the potential impact of psychological difficulties on individual wellbeing and quality of life (The National Institute for Clinical Excellence (NICE: CG15, 2004); Scottish Intercollegiate Guidance Network (SIGN: 116).

According to attachment theory (Bowlby, 1973), the attachment system is involved in regulating negative emotions that may be provoked by the appraisal of threats or danger. Human beings rely on attachment figures for help with protection, emotional support and emotional regulation, especially in the context of stressors and pain. In adolescent attachment literature, individuals with dismissing attachment tend not to engage others for emotional support and have fewer coping strategies, indicating increased risk of emotional distress; and although individuals with preoccupied attachments (characterised by a negative view of the self and positive view of others) are thought to demonstrate a willingness to engage others towards emotional support, they also tend to exhibit an internalising process in relation to mental health problems like depression, anxiety and other symptoms, which may arguably result in increased risk of emotional distress. Given what we know about fearful attachment in relation to a reluctance to seek support for diabetes management, and the shared construct of negative view of the self with preoccupied attachment, it may be hypothesised that individuals with a fearful attachment style are less likely to look to others for emotional support or help with emotional regulation, and instead deal with upsetting emotions alone. They are also more at risk of internalising mental health symptoms such as depression and anxiety. In summary, fearful attachment style may result in fewer emotional coping strategies and therefore an increased risk of emotional distress in an adolescent diabetes population. Higher levels of emotional distress and a tendency not to seek support may unsurprisingly impact upon individuals’ quality of life.

The existing evidence base for the relationship between self esteem and diabetes in adolescent populations was mixed. Some evidence suggested a positive correlation between self esteem and quality of life, with higher self esteem associated with better quality of life (de Sá Navato et al., 2007) and adolescents with many chronic diseases were found to have significantly lower self esteem (Seigel et al., 1990). However, there was also evidence of no significant relationship between diabetes and self esteem in children (Kovacs et al., 1989) and adolescents (Sullivan, 1990). The current study would
suggest no significant relationship between self esteem and Type 1 diabetes in the adolescent population.

5.2.4 Hypothesis 2

_**Wellbeing text–messaging support will result in improved metabolic control and quality of life in an adolescent population with type 1 diabetes**_

There was partial support for hypothesis 2. There was significant improvement to quality of life and a trend towards poorer metabolic control following ‘wellbeing text-messaging support’. The present study was the first of its kind to examine the impact of text-messaging support in relation to the quality of life of adolescents with type 1 diabetes. In relation to metabolic control, the current study has provided additional evidence of no effect following text-messaging support (Franklin et al., 2006) to add to the limited evidence base.

Following a review of the current literature, there is limited good quality research examining the effectiveness of text-messaging support with an adolescent type 1 diabetes population. The findings were variable in relation to HbA1c; there was some moderately strong evidence of improved HbA1c (Rami et al., 2006) and some strong evidence of no effect to HbA1c (Franklin et al., 2006). Both studies provided individually tailored advice via text-messaging to paediatric diabetes populations. One study based text-messages on self-management goals previously set in diabetes clinic (Franklin et al., 2006) and the other study based text-messaging support upon data (such as date, time, blood glucose, medication) provided by participants on a daily basis (Rami et al., 2006).

The current study used the Sweet Text system (formerly known as Sweet Talk) that was developed and described by Franklin et al. (2003, 2006). As expressed previously, the wellbeing module comprised one text-message sent each day over a three-week period. The support was therefore not individually tailored in accordance with previous literature (Franklin et al., 2006; Rami et al., 2006) which may have impacted on the lack of effectiveness found in relation to metabolic control. This type of support did, however, result in significant improvement to quality of life which may have occurred as a result of
aspects of the design such as the wellbeing content of the text-messages or the intensive presentation of the module. Further research may be useful to confirm these findings.

As previously stated, this was the first study to examine the link between text-messaging support and quality of life in an adolescent diabetes population. One relevant study, with an adult type 1 diabetes population, also found significantly improved quality of life as a result of text-messaging support (Benhamou et al., 2007), which has been supported by the present study.

Recent figures suggest that 90% of adolescents own a mobile phone and that the primary form of communication they use is text-messaging (The Mobile Phone Youth Report, 2006). Of the 60 participants that took part in the current study only one (1.7%) did not own a mobile phone. This is somewhat supported following systematic review, in that high levels of feasibility were demonstrated for the use of mobile phones or text-messaging support with an adolescent diabetes population. Thus, mobile phone technology may be suitable for use in relation to health care purposes with this population.

Further research was recommended, however, because there was some evidence to suggest the limited use of mobile phones for diabetes self management purposes by the adolescent participants (Mulvaney et al., 2012*). This finding was to some extent supported by the current study, in that 80% of the participants who provided feedback (n=12) did not want to receive any further wellbeing text-messages, though it is important to note that this feedback did not indicate a limited use of mobile phones for health care. In contrast with the current study, previous research that involved the evaluation of Sweet Text reported that 90% of the participants wanted to continue to receive messages (Franklin et al., 2006); the different text-message content that provided ‘practical’ support relating to diabetes self-care in comparison with ‘emotional’ wellbeing support in the current study, may have resulted in the contrasting findings. The need for additional research was further indicated in a study involving adolescents and their parents in which parental opinion stated that the appropriateness of the mobile phone intervention tapered off with the onset of adolescence (Gammon et al., 2005); and in another study, the authors postulated that text-messaging may lead to some anxiety in health populations by acting as ‘reminders’ of health-related difficulties (Cafazzo et al., 2012), a sentiment
echoed by a small proportion of the current study sample (n=2) who declined the offer of text-messaging support. Regardless of the suggested need for additional text-messaging research following systematic review, it is important to note that, in comparison with the other telemedical (TM) systems that were reviewed, text-messaging was often the preferred choice among adolescent diabetes participants (Tasker et al., 2007; Hanauer et al., 2009).

There was some positive feedback relating to the individual text-messages in the wellbeing module used in the current study (they made me feel better; it was as if someone cared). Since current care guidelines highlight wellbeing and quality of life as relevant to diabetes populations (NICE: CG15; SIGN: 116), ‘wellbeing text-messaging support’ and quality of life as an outcome measure may be worthy of further investigation with the adolescent diabetes population.

There were some potential confounding variables in relation to the text-messaging component of the current study that required consideration. For example, there were some technical difficulties, in that one third of the participants did not receive the full wellbeing module and almost half of the participants (46.6%) received the same message on more than one occasion, which was deemed ‘annoying’. This is in contrast to previous Sweet Text research where 20% of the participants were reported to have received the same message repeatedly (Franklin et al., 2006). This would appear to have impacted somewhat on participant emotions and may also have impacted on their satisfaction with the text-messaging system during evaluation. The intensity of the module delivery (one text per day across three weeks; some of the other Sweet Text modules are delivered once per week) may not have been the most efficient method of delivery in terms of HbA1c outcome and participant satisfaction; however the method of delivery did result in significantly improved quality of life. Further research was recommended to clarify the effectiveness of wellbeing text-messaging support in relation to HbA1c and quality of life.

Following systematic review, it was hypothesised that although mobile phones, text-messaging in particular, are used by adolescents with frequency within a ‘social’ context (The Mobile Phone Youth Report, 2006), they may not be used as readily for health care purposes by an adolescent diabetes population (Mulvaney et al., 2012). The current study provides some support for this idea since HbA1c was worse following text-messaging
support, although the current study did find significant improvement in quality of life. Further, good quality research has been recommended before any firm conclusions can be reached regarding the use of mobile phone technology with adolescents in a health care context.

5.3 Limitations and suggestions for future research

The limitations of the current study require consideration. First, the number of participants was relatively small, despite achieving sufficient power in all statistical analyses. Further, the limited post-intervention data may limit the generalisability of the results.

A number of participants who failed to attend their clinic appointment were unable to consent to taking part in the current study. Research has indicated that patients who do not attend their diabetes clinic often have poorer metabolic control and are more likely to have difficulty attending to diabetes care needs (Kaufman et al., 1999). Information about patients who failed to attend their appointment and the individuals who chose not to consent was not available in the current study; however, it is worth considering that this may have been indicative of fearful or dismissing attachment styles, individuals for whom care from others is unexpected and unwanted. Important cohort information may therefore have been missing from the analyses. For those who did consent to participate, the dropout rate was consistent with a similar study conducted with an adolescent diabetes population in Tayside (Robinson, 2008, unpublished dissertation).

The average HbA1c of the study sample was higher than the recommended guidelines, but consistent with previously reported HbA1c values from children and adolescents in the UK (Greene & Waugh, 2004), which may mean that the current study sample is representative of the adolescent diabetes population. However, it was noted that a slightly higher percentage of the current study sample achieved the recommended target compared with previous reports (Greene & Waugh, 2004), the reasons for which may be worthy of further investigation.
Some research has indicated that the use of insulin pumps is associated with better metabolic control and quality of life (Battelino et al., 2006; McMahon et al., 2005); therefore, since 26.7% of the study participants reported using an insulin pump, which is significantly higher than national prevalence statistics (Greene & Waugh, 2004), future research may seek to include additional analysis relating to the use of pump therapy. The above average use of insulin pumps in Tayside is not surprising as NHS Tayside is currently a leading UK centre for insulin pump therapy in young people with diabetes and therefore historically has access to additional funding for pump therapy (Robinson, 2008).

Existing attachment research with adolescents with diabetes included measures of parental perceptions of adolescent attachment and found maternal perceptions of adolescent attachment to be significantly associated with metabolic control; however adolescent and paternal perceptions of adolescent attachment were not significant (Rosenberg & Shields, 2009). The authors argued that this was supportive of previous findings, where parental perceptions of adolescent attachment styles were thought to be more accurate than adolescent perceptions. It is worth reiterating that the aforementioned study sample HbA1c was classified as ‘good’ (Rosenberg & Shields, 2009) and that this is unusual in adolescent diabetes research, where most of the literature, and current guidelines, indicate that metabolic control in this population tends to be ‘poor’ (Borus & Laffel, 2010; de Wit et al., 2007; Silverstein et al., 2005; Greene & Waugh, 2004). The current study found some adolescent self-perceptions of attachment were significantly associated with both metabolic control and quality of life; however, future studies may wish to consider attachment from multiple perspectives.

In relation to completing the study measures, family members were encouraged to let the participants complete the questionnaire pack independently in order to prevent biased responses. Some participants chose not to complete the measures in isolation and, given the nature of the attachment measures in particular, it is possible that the participants felt compelled to provide socially desirable responses. Positively, the use of a counterbalancing technique was felt to reduce some potentially confounding variables including order of presentation effects and fatigue.
The current study has sought to provide further evidence relating to the relationship between attachment style and type 1 diabetes in an adolescent population and to add to the literature with a measure of impact to quality of life, which was considered important in the context of current care guidelines (NICE: CG15; SIGN: 116). In addition, the current study has provided some support for the use of text-messaging with the same population and has provided additional information relating to impact on quality of life.

5.4 Clinical relevance

As evidenced by systematic review, diabetes teams are keen to find novel ways in which to engage adolescents and to find ways to improve health outcomes. The use of text-messaging support has an emerging evidence base, which has been somewhat supported by the current study; however, given the variability in the outcomes following systematic review, and the relatively small participant number in the current study, the need for ongoing research is indicated.

In the context of diabetes care guidelines (NICE: CG15; SIGN: 116), there is a need to identify some of the psychological factors that may be relevant in adolescent populations, in order to identify individuals who are most at risk. This may include individuals at increased risk of disengagement with recommended treatment plans and therefore poorer outcomes. There follows an argument for comprehensive psychological assessment and intervention as a matter of routine diabetes care towards the early identification of risk.

5.5 Conclusion

The current study has provided further evidence of a significant relationship between attachment style and metabolic control in a type 1 diabetes adolescent population. A significant relationship was also found between attachment security and quality of life in the same population, to add to existing adolescent diabetes literature. The evidence relating to quality of life was considered particularly important in the context of the current diabetes care guidelines (NICE: CG15; SIGN: 116).

The current study has highlighted a need to consider adolescent attachment styles and levels of emotional distress in a health care context. This may be undertaken as part of a
wider assessment to identify individuals most at risk of failing to engage with health care staff and for recommendations for diabetes care that may result in poorer outcomes. The importance of the role of clinical psychology within paediatric diabetes teams to provide comprehensive assessment, intervention, advice and consultation to diabetes staff teams is therefore considered essential.

Wellbeing support delivered via text-messaging significantly improved the quality of life of adolescents with type 1 diabetes; however, there was also a trend noted towards poorer metabolic control. The variability in outcomes and significant diversity in the types of telemedical support that were identified following systematic review, indicates a need for further, good quality research. Of particular importance is whether text-messaging can consistently result in improved outcomes in adolescents with type 1 diabetes or whether text-messaging may be regarded as a predominantly ‘social’ tool among adolescents.
Chapter 6

Journal article

Presented as a self-contained piece of work in relation to tables and references

Word count

5390

(as per Pediatric Diabetes Author Guidelines, appendix 11)
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6.1 Abstract

Objectives:
Diabetes research has indicated an association between attachment security and metabolic control as well as increased prevalence of mental health difficulties in diabetes populations. There is limited research with an adolescent Type 1 diabetes population. The current study aimed to examine attachment, emotional distress and self-esteem in an adolescent Type 1 diabetes population in relation to metabolic control and quality of life. The current study also aimed to evaluate the impact of ‘wellbeing text-messaging support’ with the same population.

Method
60 participants aged between 12-18 years old who had a diagnosis of Type 1 diabetes for over 12 months took part. A longitudinal questionnaire design was used to collect data using five validated psychological measures. HbA1c was used as a measure of metabolic control. Text-messaging comprised a wellbeing module delivered daily over a three-week period.

Results
High levels of fearful attachment security predicted poorer metabolic control and poorer quality of life, and high levels of emotional distress predicted poorer quality of life.
‘Wellbeing text-messaging support’ resulted in significantly improved quality of life.

Conclusion
Adolescent attachment style and emotional distress may be assessed as part of routine diabetes care in order to identify individuals who are potentially most at risk of failing to engage with diabetes health care, which may subsequently impact negatively on metabolic control and/or quality of life. These findings highlight the importance of clinical psychology input in paediatric diabetes teams. Further research in relation to text-messaging support was recommended.
6.2 Introduction

Diabetes mellitus is a highly prevalent and costly chronic health condition that can result in severe health-related complications including heart disease, stroke and blindness. There are two main types of diabetes, Type 1 and Type 2. Recent research has estimated prevalence of diabetes in the UK to be 4.45% of the population (2.9 million people; 1) and for individuals with Type 1 diabetes, there has been a steady increase in numbers, reflecting the rise in the incidence of diabetes in Scottish children, which is said to have risen by 2-3% per year since 1968 (2). The vast majority of children and young people who have diabetes have Type 1 diabetes, and the peak age of diagnosis is reported as 10-14 years old (1).

The National Institute for Clinical Excellence (NICE) in collaboration with the National Collaborating Centre for Women and Children’s Health (NCCWCH) recommend an integrated and ongoing package of care for Type 1 diabetes (3) that involves access to a comprehensive management plan including insulin treatment. NICE and the Scottish Intercollegiate Guidance Network (SIGN) also recommend access to mental health professionals due to the potential risk that psychological factors, such as anxiety and depression may have on diabetes management, wellbeing and quality of life (4). Despite clear guidelines, strict metabolic control is hard to accomplish for children and young people (5) and, in adolescence in particular, it has been widely reported that metabolic control decreases significantly (6-9). The adolescent period is defined by the World Health Organisation (WHO) as between 10-19 years of age (10). Difficulties with diabetes management are particularly important since the patterns established in adolescence are likely to continue into adulthood and may therefore impact on health in the longer-term (11); therefore, there is a need to better understand the psychological factors that may impact diabetes management in a bid to facilitate feasible, practical ways to improve metabolic control in the adolescent diabetes population.

This study seeks to delineate how attachment security may impact upon metabolic control and quality of life in adolescents with Type 1 diabetes. According to Bowlby’s Attachment Theory, children internalise experiences with caretakers in such a way that early attachments form a prototype for later relationships outside the family (12) and
evidence suggests these remain stable across the life span (12-14). Drawing on this, Bartholomew & Horowitz (13) described a model of attachment styles to include two types of internal working models: an internal model of the self and others, each with a negative and positive view yielding four attachment styles, secure, fearful, preoccupying and dismissing. In brief, the nature of an individual’s attachment style can impact upon how they relate to others, which may be relevant in interactions that take place within a health care setting.

Ciechanowski and colleagues used the Bartholomew & Horowitz model (13) with an adult diabetes population and found attachment security to be significantly associated with metabolic control (15, 16). They found individuals with high levels of dismissing attachment were at greater risk of poor metabolic control compared with individuals who reported high levels of secure attachment (15). Individuals with high levels of preoccupied attachments were found to be at lower risk of elevated levels of HbA1c, said to be due to willingness to seek input from others in healthcare (16). Additional research indicated an impact of psychological factors relative to attachment security classification in an adult diabetes population (17).

There is limited literature that has investigated the relationship between attachment security and diabetes in an adolescent population. A recent study (Henderson, 2010, unpublished dissertation), provided evidence of a predictive relationship between attachment security and metabolic control; additional psychological factors, including depression and anxiety, were found not to impact metabolic control. Another study found evidence of a significant association between secure attachment and better metabolic control (18). In relation to psychological factors in adolescents with diabetes, evidence would suggest increased prevalence of depression, anxiety and lower self esteem in comparison with non-diabetes populations (19-21).

Health-related quality of life (QOL) measurement has emerged as an important health outcome in diabetes research, which corresponds with the recommendations made by current care guidelines (3, 4). However, to date no studies have directly investigated the relationship between attachment and quality of life in an adolescent diabetes population until now.
Over 90% of all adolescents in the UK own a mobile phone (22). There is some support for the potential use of text-messaging support as a tool for improved outcomes in adolescent diabetes populations (23, 24). The *Sweet Text* text-messaging system (formerly known as *Sweet Talk*: 23, 25) was used in the current study to implement a novel wellbeing module (see Table 1 for examples of wellbeing text messages).

Text-messaging support has resulted in improved QOL in an adult diabetes population (26). To date, no studies have evaluated the impact of text-messaging support on the QOL of an adolescent diabetes population.

**Table 1: Examples of Sweet Text wellbeing text messages**

<table>
<thead>
<tr>
<th>Do something you really enjoy every day</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you’re feeling down re your diabetes, chat to someone you know can help you to feel better</td>
</tr>
<tr>
<td>You can improve your diabetes by making small changes to your lifestyle</td>
</tr>
<tr>
<td>Think about at least one thing you are good at</td>
</tr>
<tr>
<td>There are lots of people like you who have diabetes</td>
</tr>
<tr>
<td>Feeling sad sometimes is normal. What can you do to make yourself feel better?</td>
</tr>
</tbody>
</table>

6.2.1 Aim

This was the first study to comprehensively test the predictive role of the psychological factors attachment, emotional distress and self esteem in adolescents with Type 1 diabetes, in relation to metabolic control (as measured by HbA1c) and QOL. This was also the first study to evaluate ‘wellbeing text-messaging support’ in relation to HbA1c and QOL in the same population.
6.3 Method

6.3.1 Design

A longitudinal, questionnaire design was used. The East of Scotland Research Ethics Service (EoSREC) REC1 approved the study.

6.3.2 Power calculation

Based on a-priori sample size calculation for multiple regression, at the significance alpha level of 0.05, a medium anticipated effect size (0.15) and a desired statistical power level of 0.8, for the 6 assessment scales and subscales to be statistically analysed as predictors, a sample size of 73 was indicated (27).

6.3.3 Participants

Adolescent paediatric patients attending clinics in Tayside, Scotland were invited to participate if they were aged between 12 and 18 years (inclusive) and had been diagnosed with Type 1 diabetes for at least one year. Patients who had a diagnosed psychiatric disorder or intellectual disability were excluded. Participants were recruited between February and June 2012. A letter of invitation and information sheet was posted to prospective participants prior to their review appointments.

6.3.4 Measures

All of the participants who provided written consent to take part completed a questionnaire pack to include the collection of demographic information (age, gender, date of diagnosis and method of insulin delivery) and four validated psychological measures suitable for an adolescent population. The measures were completed during routine clinic appointments and are detailed as follows:
Adolescent Relationship Questionnaire (A-RQ: 28)
The A-RQ self-report questionnaire, previously adapted for use by an adolescent population, was used to provide categorical and continuous measures of attachment style. The A-RQ comprised four statements that correspond with secure, fearful, preoccupied and dismissing attachment styles. Participants chose which statement most reflected their attachment style (categorical) before rating their strength of agreement to each statement using a standard Likert scale (range 1-7; continuous).

Paediatric Index of Emotional Distress (PI-ED: 29)
The PI-ED 14-item questionnaire (based on the Hospital Anxiety and Depression Scale; 30) provided a single measure of emotional distress. Participants scored each item based on how they had been feeling over the last week (range 0-3). A higher score indicated greater levels of distress. In the current study, alpha reliability was .84.

The Self Image Profile for Adolescents (SIP-A: 31)
The SIP-A self-report questionnaire was designed to measure self image and self esteem in 12-16 year olds. Through two ratings, the 25-item Likert scale (range 0-6) provided a measure of positive self image (+SI), negative self image (-SI) how I think I am, and a measure of self esteem, which was estimated by the discrepancy between ratings of how I think I am and how I would like to be. A higher score on the self esteem scale indicated lower self esteem. The self esteem component had an alpha reliability of .90 in the current study.

Pediatric Quality of Life Inventory (PedsQL-Diabetes module 3.0: 32)
The PedsQL Inventory designed for 13-18 year olds with Type 1 diabetes comprised a 28-item Likert scale questionnaire which identifies 5 scales: diabetes symptoms, treatment barriers, treatment adherence, worry and communication. Participants scored each item based how frequently the item had been a problem over the last month. Higher scores indicated fewer symptoms or problems. In the current study, alpha reliability was .90.
To reduce the chances of order of presentation or fatigue impacting upon the results, the four psychological measures were counterbalanced using a procedure informed by a balanced Latin Square approach (33).

**Text-messaging**

The participants were commenced onto the wellbeing module of *Sweet Text* in the week following their clinic appointment. The wellbeing module was new. From a sample of 45 messages, one text message was sent to participants’ mobile phones every day over a three week period.

**Primary Outcome Measures**

The primary outcome measures were metabolic control (as measured by HbA1c) and quality of life (PedsQL). HbA1c was collected by the specialist diabetes team as per routine care. HbA1c values were collected from patients’ medical files at initial and subsequent clinic appointments.

The PedsQL and an evaluative questionnaire, designed to measure satisfaction with the wellbeing module, were posted to participants following completion of the module with a stamped addressed envelope for their return.
6.4 Results

The progress of participants through the study is shown in Figure 1. From 89 eligible participants, 14 did not consent to take part and 15 did not attend their review appointment. 60 participants took part in the questionnaire component of the study and, of those, 57 completed the entire study (3 participants declined text messaging support because they did not own a mobile phone (n=1) or they did not want ‘reminded’ that they have diabetes (n=2).

6.4.1 Demographic and clinical data

Of the 60 participants, 37 (62%) were female and the mean age of the sample was 15.23 years (range 12-18), SD 1.701. The average length of diagnosis was 7.02 years (range 1-15), SD 3.99. Forty four (73.3%) participants used injections to deliver their insulin treatment and the remaining 16 (26.7%) used an insulin pump. The average HbA1c was 77.52 mmol/mol units (SD=19.95; range 41-125; International Federation of Clinical Chemistry (IFCC). This was higher than the recommended optimal value of HbA1c (<58mmol/mol; IFCC units) indicating poor metabolic control. The majority of the study sample (n=53: 88%) had higher than the recommended HbA1c.

6.4.2 Missing Values Analysis (MVA)

MVA (SPSS, version 19.0) showed that no pre-intervention variables had >5% missing data therefore no data transformations were indicated. The statistical package used reduced the number of complete data sets analysed by two (n=58) which may have been as a result of two full measures that were not completed. No kurtosis or significantly skewed variables were indicated.
89 Eligible Participants

14 refused consent

15 did not attend their clinic appointment

60 participants consented and completed the questionnaire component of the study

3 participants declined text-messaging support for the following reasons:
  - Did not own a mobile phone (n=1)
  - Did not want ‘reminders’ of diabetes status (n=2)

57 participants completed the entire study, including questionnaire and text-messaging components

Figure 1: Flow of participants through the study
6.4.3 Primary outcomes

To determine whether HbA1c and Quality of Life could be predicted on the basis of attachment security, emotional distress and self esteem, two hierarchical regressions (one for each criterion variable) were conducted.

6.4.3.1 HbA1c

Regression analysis showed that the variables that entered the regression equation accounted for 19% of the variance in HbA1c (adjusted R square = .190; F 2,55 = 7.66, p<0.001, using the stepwise method). Age accounted for 1.8% of the variance and fearful attachment (as measured by the A-RQ) accounted for a further 17.2% of the variance. The size and direction of the relationships suggest participants who reported high levels of fearful attachment had poorer metabolic control (higher HbA1c levels). Self esteem, emotional distress and the remaining attachment styles (secure, preoccupied and dismissing) did not significantly impact HbA1c.

In relation to the HbA1c regression model, effect size calculations (Cohen’s $f^2$) revealed a large effect size of 0.28 and power (1 – $\beta$) of 0.79, which indicates that the analysis was sufficiently powered.

6.4.3.2 Quality of Life

Regression analysis demonstrated that the variables that entered the regression equation accounted for 52.6% of the variance in quality of life (adjusted R square = .526; F 3,54 = 22.11, p<0.001, using the stepwise method). Age accounted for 1.6% of the variance, emotional distress (as measured by the PI-ED) accounted for a further 46.3%, and fearful attachment (as measured by the A-RQ) accounted for the remaining 4.7% of the variance. The size and direction of the relationships suggest participants who have high levels of fearful attachment and higher levels of emotional distress will have poorer quality of life (as indicated by a lower score on PedsQL). Self esteem and the remaining attachment styles (secure, preoccupied and dismissing) were not significant predictors in this model.
In relation to the quality of life regression model, effect size calculations (Cohen’s $f^2$) revealed a very large effect size of 1.22 and power ($1 – \beta$) of 0.99, which indicates that the analysis was sufficiently powered.

6.4.3.3 Text-messaging support

Paired samples t-tests demonstrated significant improvement to QOL ($t = 1.938$, df = 15, $p=.036$, one-tailed) following ‘wellbeing text-messaging support’. The magnitude of the difference in the means ($d=0.31$) indicated a small to moderate effect size. A trend towards poorer HbA1c was also found ($t = 1.703$, df = 20, $p=.052$, one-tailed). The magnitude of the difference in the means ($d=0.16$) indicated a small effect size.
6.5 Discussion

On average, metabolic control in the adolescent Type 1 diabetes population in Tayside was found to be poor; however, it was consistent with reported HbA1c levels in children and adolescents across the UK (9). The proportion of adolescents whose HbA1c was in the healthy range (11.6%) was higher than the reported average (9) though the reasons for this were not clear. One possible explanation was the level of insulin pump use in the current study, which was higher than the national average (26.7%). According to recent research, the use of insulin pumps is associated with better metabolic control and quality of life (34, 35). Future research may include analysis relating to level of pump use.

6.5.1 HbA1c

The current study provided further evidence of a significant relationship between attachment and metabolic control in an adolescent Type 1 diabetes population (Henderson, 2010; 18).

Fearful attachment style was found to predict poorer metabolic control in the current study. Individuals with a fearful attachment style are hypothesised to have a negative view of the self and others as a result of rejecting-style care-giving, leading to the likelihood of approach-avoidance interpersonal behaviour in health care settings (16). In health care, a negative view of the self may manifest itself as an inability to demonstrate or to prioritise self-care, which is an integral part of diabetes management. A negative view of others may result in a failure to seek care from others, and that may include health care providers and/or family members. In relation to health care, this may result in increased frequency of missed appointments and, during direct contact, poorer collaborations including, for example, failure to elaborate on worsening symptoms that may elicit input and prompt tailored care. Seeking care from family members may be particularly important in adolescents, since diabetes care has been found to be predominantly the responsibility of the family and parents in early adolescence (36). Thus, for individuals with high levels of fearful attachment, the inability to prioritise self-care as well as neglecting to seek support from others, either in health care or family, may impact on their ability to manage a complex, chronic illness like Type 1 diabetes which
may, in turn, impact upon metabolic control. Linking with recent evidence, good metabolic control has also been associated with better quality of life (37, 38),

6.5.2 Quality of life

No previous research has investigated the relationship between attachment security and quality of life, as well as emotional distress and self esteem, in the adolescent Type 1 diabetes population. In the current study, higher levels of fearful attachment and high levels of emotional distress were found to significantly predict poorer quality of life.

Type 1 diabetes requires intensive daily management tasks, such as managing blood glucose and insulin administration, therefore adolescents with diabetes face many challenges on a daily basis. It may be hypothesised that the level of daily challenges experienced may interfere with ‘normal’ relationships and activities and therefore potentially quality of life (QOL). This has been reflected in the emergence of health-related QOL measurement as an important health outcome in clinical trials, clinical practice improvement strategies and healthcare service research and evaluation (38) which also corresponds with current diabetes care guidelines in which emphasis is placed on the potential impact to quality of life (3, 4). As discussed, individuals with fearful attachment are less likely to seek support from either self or others. When the same individuals are coping with the intensive daily management required for diabetes without support, from family members or health care providers, they may miss out on appropriate treatment or advice towards improving outcomes, which may act as an obstacle to achieving optimal quality of life. The significant relationship found between fearful attachment and quality of life in the current study has highlighted an important relationship and a need for further research with this population.

Adolescent diabetes literature has suggested increased prevalence of psychological difficulties, such as depression, anxiety and lower self esteem in comparison with non-diabetes populations which may provide some explanation for the current findings (19-21). Further, in the context of attachment theory, negative emotions are said to be regulated by the attachment system (39) with individuals learning how to engage in self-soothing routines based on interactions with others (40). Individuals with high levels of fearful attachment have usually experienced rejecting-style care-giving and often, as a
result, find it more difficult to regulate their emotions; these individuals are more likely to deal with upsetting emotions without self-soothing or seeking support from others. Further, research would suggest that these individuals are more at risk of internalising mental health symptoms such as depression and anxiety (41-43) which may in turn impact upon levels of emotional distress. Thus, the increased levels of emotional distress and significant impact to quality of life in the current study may be as a result of increased prevalence of psychological difficulties as well as an underlying lack of ability to regulate emotion due to individual attachment style. This is an important finding and one that highlights a need for mental health assessment and treatment as an integral part of diabetes care, particularly in the context of current diabetes care guidelines (3, 4).

The existing evidence base for the relationship between self esteem and diabetes in adolescent populations was mixed, with some evidence of a positive correlation between self esteem and quality of life (44) and no evidence of a significant relationship between self esteem and diabetes (45). The current study indicated no significant effect of self esteem in relation to quality of life or HbA1c in a Type 1 diabetes adolescent population.

6.5.3 Text-messaging

There was significant improvement to quality of life and a trend towards poorer metabolic control (indicated by increased HbA1c) following ‘wellbeing text-messaging support’. The present study was the first of its kind to examine the impact of text-messaging support on the quality of life of adolescents with Type 1 diabetes. The improved QOL may have occurred as a result of aspects of the design such as the wellbeing content of the text-messages or the intensive presentation of the module; further research may be useful to confirm these findings. The trend towards poorer metabolic control was important to add to existing literature and may cast some doubt as to the effectiveness of text-messaging support towards improved health outcomes in an adolescent diabetes population. One possible explanation was that mobile phones are used predominantly in a ‘social’ context in the adolescent population and perhaps less for health care purposes. This idea has had some support from a recent study in which Type 1 diabetes adolescents reported limited use of mobile phones for diabetes management purposes (46). In the current study, of the 15 participants who provided an evaluation of text-messaging support, the majority of those (n=12: 80%) declined the offer of further
‘wellbeing text-messaging support’, despite significant improvement to quality of life; this is in contrast to previous ‘Sweet Text’ research, where 90% of participants wanted to continue to receive text-messages (23). It was hypothesised this may be due to the contrasting information provided, for example, ‘emotional’ wellbeing information compared with, previously, ‘practical’ diabetes self-management information. Thus, further research has been recommended, in particular to ascertain whether mobile phones may be feasible for use for healthcare purposes with the adolescent diabetes population.

6.5.4 Limitations and suggestions for future research

There were a number of limitations that required consideration. First, the number of participants was relatively small, despite achieving sufficient power in all statistical analyses. Also, there was no information gathered relating to the participants who declined to take part or who did not attend their clinic appointment, resulting in potentially important missing cohort information. Further, the limited amount of post-intervention data may limit the generalisability of the results.

Regarding the text-messaging support, there were a number of technical difficulties noted, for example one third of participants did not receive the entire wellbeing module and almost half of the participants (46.6%) received the same message more than once, which was considerably higher than previous Sweet Text research (20%; 23). These difficulties may have impacted somewhat on outcomes as well as participant satisfaction.

6.6 Conclusion

The current study has provided evidence of a significant relationship between fearful attachment style and metabolic control in an adolescent Type 1 diabetes population. Further, the significant relationship found between fearful attachment and quality of life, and emotional distress and quality of life, provides important evidence to add to the existing literature. This evidence was considered particularly important in the context of the current diabetes care guidelines, where emphasis has been placed on the potential impact that diabetes may have on quality of life (3, 4).
The findings have highlighted the need to consider adolescent attachment styles and levels of emotional distress within a health care context. This may be undertaken as part of a wider assessment to identify individuals most at risk of failing to engage with health care staff and recommendations made towards diabetes care that may result in poorer outcomes. The importance of the role of clinical psychology within paediatric diabetes teams to provide comprehensive assessment, intervention, advice and consultation to diabetes staff teams is considered essential following the current study.

Wellbeing text-messaging support significantly improved quality of life in the study sample; however, further research has been recommended to confirm the current findings.
6.7 References

1. Diabetes in the UK, 2012. Available from:

2. NHS Scotland. Scottish Diabetes Survey. 2012. Available from:
   http://www.diabetesinscotland.org.uk/Publications/SDS%202010.pdf


7. Main references


Dear Ms Swan

Full title of study: To what extent do attachment security, self-esteem, mood and anxiety predict better outcome on the glycaemic control and quality of life of adolescents with type 1 diabetes, following wellbeing support provided via a text-messaging system?

REC reference number: 11/ES/0053

Thank you for your letter of 13 January 2012, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

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, subject to the conditions specified below.

Ethical review of research sites

NHS 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" below).

Non-NHS sites

Conditions of the favourable opinion

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

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).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

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<tr>
<th>Document</th>
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<td>Evidence of insurance or indemnity</td>
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<td>Other: CV - Professor Michael Power</td>
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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 NRES 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 website.

Further information is available at National Research Ethics Service website > After Review

11/ES/0053  Please quote this number on all correspondence

Yours sincerely

Dr Carol Macmillan
Chair

Email: lorraine.reilly@nhs.net

Enclosures:  "After ethical review – guidance for researchers"

Copy to:  Dr Lynn Morrice, University of Edinburgh
          NHS Tayside R&D Office
24 January 2012

Ms Mary Swan
Doctoral Trainee in Clinical Psychology
NHS Tayside/University of Edinburgh
Centre for Child Health
19 Dudhope Terrace
Dundee
DD3 6HH

Dear Ms Swan

R & D MANAGEMENT APPROVAL – TAYSIDE

Title: To what extent do attachment security, self-esteem, mood and anxiety predict better outcome on the glycaemic control and quality of life of adolescents with type 1 diabetes, following wellbeing support provided via text-messaging system?

Chief Investigator: Ms Mary Swan         Local Collaborator: Dr Vicki Robinson

Tayside Ref: 2011PZ11         NRS Ref: N/A

REC Ref: 11/ES/0053

Sponsor: University of Edinburgh

Funder: Unfunded

Many thanks for your application to carry out the above project here in NHS Tayside. I am pleased to confirm that the project documentation (as outlined below) has been reviewed, registered and Management Approval has been granted for the study to proceed locally in Tayside.

Approval is granted on the following conditions:-

• ALL Research must be carried out in compliance with the Research Governance Framework for Health & Community Care, Health & Safety Regulations, data protection principles, statutory legislation and in accordance with Good Clinical Practice (GCP).

• All amendments to be notified to TASC R & D Office.

• All local researchers must hold either a Substantive Contract, Honorary Research Contract, Honorary Clinical Contract or Letter of Access with NHS Tayside where required (http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx).

• TASC R & D Office to be informed of change in Principal Investigator, Chief Investigator or any additional research personnel locally.

• Notification to TASC R & D Office of any change in funding.
• As custodian of the information collated during this research project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT Security Policies, until destruction of this data.

• Recruitment numbers on a quarterly basis to be reported to TASC R & D Office.

• Annual reports are required to be submitted to TASC R & D Office with the first report due 12 months from date of issue of this management approval letter and at yearly intervals until completion of the study.

• Notification of early termination within 15 days or End of Trial within 90 days followed by End of Trial Report within 1 year to TASC R & D Office.

• You may be required to assist with and provide information in regard to audit and monitoring of study.

Please note you are required to adhere to the conditions, if not, NHS management approval may be withdrawn for the study.

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May I take this opportunity to wish you every success with your project.

Please do not hesitate to contact TASC R & D Office should you require further assistance.

Yours sincerely

Elizabeth Coote
R&D Manager

Tayside medical Science Centre (TASC)
Ninewells Hospital & Medical School
Dear Young Person

You have been invited to take part in a research project with the aim to better understand metabolic control and quality of life for young people with type 1 diabetes. The research is being undertaken as part of a Doctorate of Clinical Psychology at the University of Edinburgh from December 2011 to August 2012.

It would be much appreciated if you could read the enclosed information sheets prior to your next routine diabetes clinic appointment. If you have any questions or queries regarding the research, please do not hesitate to get in touch with Mary Swan, Researcher/Trainee Clinical Psychologist, contact details above.

The research is entirely voluntary and your diabetes care will not be affected in any way should you choose to participate, choose not to participate or withdraw from the study at any point.

Should you decide to take part, your written consent will be obtained and a number of short questionnaires will be given to you to complete whilst waiting for your next routine diabetes clinic appointment. All questionnaires are entirely anonymous and confidential. The Researcher will be present to answer any questions you may have.

Please do not hesitate to get in contact should you have any questions at this time, with either the Researcher or Dr Vicki Robinson, at the above address. Thank you for reading this letter.

Yours sincerely

Mary Swan
Researcher/Trainee Clinical Psychologist
Version 1 – 30/11/11
Appendix 3b

Psychological factors and text support in adolescent diabetes
Young person Information Sheet

My name is Mary Swan and I am a Doctoral Student at the University of Edinburgh. I am required to complete a project as part of my course and invite you to take part in the following study. However, before you decide to do so, I need to be sure that you understand firstly why I am doing it, and secondly what it would involve if you agreed. I am therefore providing you with the following information. Please read it carefully and be sure to ask any questions you might have and, if you want, discuss it with others including your friends and family. I will do my best to explain the project to you and provide you with any further information you may ask for now or later.

What is the purpose of the study?
As you may know, the close monitoring and maintenance of blood sugar levels can result in improved metabolic control which can in turn lead to fewer complications (e.g. circulation difficulties, renal failure) and higher levels of general health and quality of life. Many studies have found that, during adolescence, metabolic control can become poorer and more difficult to control for many individuals.

Some factors that are known to effect metabolic control include family relationships, levels of self-esteem, mood and anxiety. Some recent studies have found that receiving support via mobile phone has helped improve the metabolic control of people who have diabetes. As a result, the Sweet Text text-messaging system has recently been introduced in Tayside and you may already have had some experience of receiving texts via Sweet Text.

This study aims to investigate whether some of the factors mentioned, like mood and anxiety, are able to predict your metabolic control and whether regular text-messaging support will improve metabolic control and also quality of life.

Why have I been chosen?
All young people with Type 1 diabetes (aged 12-18) attending for review at the Diabetes Clinics in Tayside (including Ninewells Hospital, Perth Royal Infirmary and Arbroath Infirmary) will be invited to take part. The study will be undertaken over a period of 12 months.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do take part you will be given a copy of this information sheet to keep and you will be asked to sign a consent form. Your parent/guardian will also be given an Information Sheet to read and will be asked to provide their consent (if you are under 16 years old). You will be free to withdraw from the study at any time, you do not have to give a reason and it will not affect the care you receive at the diabetes clinic. To withdraw from the study, you can either inform the researcher or a member of the clinical staff team. All information that has been collected up to that point would no longer be used in the study.

What will happen to me if I take part?
You would be asked to complete a questionnaire pack while you are at the diabetes clinic for your routine review. This should take approximately 20-30 minutes to complete. You will then receive regular texts from the diabetes team for approximately 4 weeks, after which a short questionnaire with return envelope will be sent out.
for you to complete and return. Your HbA1c results, which are gathered at each review appointment, will be recorded on two occasions. All of the information collected will remain confidential/private.

What are the possible disadvantages, risks or benefits of taking part?
There are no foreseen disadvantages or risks from taking part in this study. Benefits may include receiving support via a text-messaging system and the opportunity to be part of a study which aims to better understand some of the factors that may affect metabolic control in young people with diabetes.

Will my taking part in this study remain confidential/private?
All of the information collected about you during the study will be kept strictly confidential, for example, your name and address will be removed from any documents so that you cannot be recognised. Your information will be stored on a password protected computer and your identity will only been known by members of the research team. When the results are reported no names will be included and all of the study information will be stored securely in NHS Tayside Child and Adolescent Psychology Department for 5 years.

What will happen to the results of the research study?
The results of the study will count towards my Doctoral qualification for the University of Edinburgh which is to be handed in during August 2012 and may be published subsequently. A summary of the results will be available sometime after August 2012. If you would like a copy of the summary, please contact the researcher.

Who is organising and funding the research?
The research is being undertaken for the purposes of a Doctor of Clinical Psychology thesis sponsored by the University of Edinburgh and NHS Tayside. The researcher will not be paid specifically for undertaking this research.

Who has reviewed this study?
The East of Scotland Research Ethics Committee REC 1, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant records, be made available for scrutiny by monitors from the University of Edinburgh and NHS Tayside, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

What are my rights?
If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through the University of Edinburgh who are acting as the research sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Patient Liaison Manager, Complaints Office, Ninewells Hospital (Freephone 0800 027 5507). Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS Tayside but you may have to pay your legal costs.

Contact for further information
Please feel free to contact the researcher, Mary Swan, or Dr Vicki Robinson, Clinical Psychologist, if you have any further questions regarding the study. Contact details for both individuals are as follows:

Mary Swan
Trainee Clinical Psychologist
Centre for Child Health
19 Duchess Terrace
Dundee
DD3 6HH
Tel: 01382 346565/346553
Mary.swan1@nhs.net

Thank you for taking the time to read this Information Sheet. Please keep a copy of this and the signed consent form for your records.
Appendix 3c

Psychological factors and text support in adolescent diabetes
Parent/Guardian Information Sheet

My name is Mary Swan and I am a Doctoral Student at the University of Edinburgh. I am required to complete a project as part of my course and invite your child to take part in the following study. However, before you decide if you agree to them doing so, I need to be sure that you understand firstly why I am doing it, and secondly what it would involve if you and your child agreed. I am therefore providing you with the following information. Please read it carefully and be sure to ask any questions you might have and, if you want, discuss it with others including your friends and family. I will do my best to explain the project to you and provide you with any further information you may ask for now or later.

What is the purpose of the study?
As you may know, the close monitoring and maintenance of blood sugar levels can result in improved metabolic control which can in turn lead to fewer complications (e.g. circulation difficulties, renal failure) and higher levels of general health and quality of life. Many studies have found that, during adolescence, metabolic control can become poorer and more difficult to control for many individuals.

Some factors that are known to affect metabolic control include family relationships, levels of self-esteem, mood and anxiety. Some recent studies have found that receiving support via mobile phone has helped improve the metabolic control of people who have diabetes. As a result, the Sweet Text text-messaging system has recently been introduced in Tayside and your child may already have had some experience of receiving texts via Sweet Text.

This study aims to investigate whether some of the factors mentioned, like mood and anxiety, are able to predict your child's metabolic control and whether regular text-messaging support will improve metabolic control and also quality of life.

Why has my child been chosen?
All young people with Type 1 diabetes (aged 12-18) attending for review at the Diabetes Clinics in Tayside (including Ninewells Hospital, Perth Royal Infirmary and Arbroath Infirmary) will be invited to take part. The study will be undertaken over a period of 12 months.

Does my child have to take part?
No. It is up to you and your child to decide whether or not to take part. If your child does decide to take part, you and your child will be given a copy of an information sheet to keep and you will be asked to sign a consent form (if your child is under 16 years of age). Your child will also be asked to provide their consent. Thereafter your child will be free to withdraw from the study at any time without giving a reason and without it affecting the care they receive at the diabetes clinic. For your child to withdraw from the study, they or you can either inform the researcher or a member of the clinical staff team. All information that has been collected up to that point would no longer be used in the study.

What will happen to my child if they take part?
Your child would be asked to complete a questionnaire pack while at the diabetes clinic for routine review. This should take approximately 20-30 minutes to complete. Your child will then receive regular texts from the diabetes team for approximately 4 weeks, after which a short questionnaire with return envelope will be sent out.
for your child to complete and return. Your child’s HbA1c results, which are gathered at each review appointment, will be recorded on two occasions. All of the information collected will remain confidential.

**What are the possible disadvantages, risks or benefits of taking part?**
There are no foreseen disadvantages or risks from taking part in this study. Benefits may include your child receiving support via a text-messaging system and the opportunity to be part of a study which aims to better understand some of the factors that may affect metabolic control in young people with diabetes.

**Will my child taking part in this study remain confidential?**
All of the information collected about your child during the study will be kept strictly confidential, for example, their name and address will be removed from any documents so that they cannot be recognised. Your child’s information will be stored on a password protected computer and their identity will only be known by members of the research team. When the results are reported, no names will be included and all of the study information will be stored securely in NHS Tayside Child and Adolescent Psychology Department for 5 years.

**What will happen to the results of the research study?**
The results of the study will form my Doctoral Thesis which is to be handed in during August 2012 and may be published subsequently. A summary of the results will be available sometime after August 2012. To obtain a copy of the summary, please contact the researcher.

**Who is organising and funding the research?**
The research is being undertaken for the purposes of a Doctor of Clinical Psychology thesis sponsored by the University of Edinburgh and NHS Tayside. The researcher will not be paid specifically for undertaking this research.

**Who has reviewed this study?**
The East of Scotland Research Ethics Committee REC 1, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant records, be made available for scrutiny by monitors from the University of Edinburgh and NHS Tayside, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

**What are my child’s rights?**
If you believe that your child has been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through the University of Edinburgh who are acting as the research sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Patient Liaison Manager, Complaints Office, Ninewells Hospital (Freephone 0800 027 5507). Note that the NHS has no legal liability for non-negligent harm. However, if your child is harmed and this is due to someone’s negligence, you may have grounds for a legal action against NHS Tayside but you may have to pay your legal costs.

**Contact for further information**
Please feel free to contact the researcher, Mary Swan, or Dr Vicki Robinson, Clinical Psychologist, if you have any further questions regarding the study. Contact details for both individuals are as follows:

Mary Swan  
Trainee Clinical Psychologist  
Centre for Child Health  
19 Dudhope Terrace  
Dundee  
DD3 8HH  
Tel: 01382 346565/346553  
Mary.swan1@nhs.net

Thank you for taking the time to read this Information Sheet. Please keep a copy of this and the signed consent form for your records.
YOUNG PERSON CONSENT FORM

Title of Project: Psychological factors and text support in adolescent diabetes
Name of researcher: Mary Swan

Please initial the boxes next to each of the following statements:

1. I confirm that I have read and understand the information sheet dated 06/01/12 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had any questions answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without my medical care or legal rights being affected. I understand that if I withdraw, any information that has been collected will not be included in the study.

3. I understand that my participation in this study will involve completing questionnaires on psychological factors and quality of life.

4. I understand that sections of any of my medical notes may be looked at by responsible individuals from NHS Diabetes Clinics or the Researcher where it is relevant to my taking part in research. I give permission for the Researcher and members of my routine Diabetic Team to have access to my records in order to obtain my HbA1c results.

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

Name of Young Person.................................................................Date..........................
Young Person's signature......................................................Name of Parent/guardian .....................................................Date..........................

Name of person taking
Consent.........................................................Designation.....................................................Date..........................
Signature..........................................................Date........................................................

NB Three copies should be made for (1) young person and family, (2) researcher, (3) hospital notes

Centre number...................Identification number for this study
Appendix 3e

PARENT/GUARDIAN CONSENT FORM

Title of Project: Psychological factors and text support in adolescent diabetes
Name of researcher: Mary Swan

Please initial the boxes next to each of the following statements:

1. I confirm that I have read and understand the information sheet dated 06/01/12 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had any questions answered satisfactorily.

2. I understand that my child's participation is voluntary and that they are free to withdraw at any time, without their medical care or legal rights being affected. I understand that, if my child withdraws, any information that has been collected will not be included in the study.

3. I understand that my child's participation in this study will involve completing questionnaires on psychological factors and quality of life.

4. I understand that sections of my child's medical notes may be looked at by responsible individuals from NHS Diabetes Clinics or the Researcher where it is relevant to my child taking part in research. I give permission for the Researcher and members of my child's routine Diabetic Team to have access to my child's records in order to obtain my child's HbA1c results.

5. I agree for my child to take part in the above study.

Name of Young Person

Parent/guardian signature...Date...

Name of person taking Consent...Designation...
Signature...Date...

NB Three copies should be made for (1) young person and family, (2) researcher, (3) hospital notes

Centre number...Identification number for this study...
Thank you for taking part in this research.

Please answer as many of the following questions as honestly as you can. If you have any questions, please ask a member of staff for help.

Are you Female/Male (please circle)

How old are you today? ___________ years ___________ months

When were you diagnosed with diabetes? ___________ / ___________ (mm/yyyy)

How do you take your insulin? Injections/Insulin pump (please circle)

Where is your diabetic clinic appointment today? ___________ (Dundee/Perth/Arbroath)

Do you have any diagnosed Psychiatric Disorders? Yes/No (please circle)

If yes, which disorder(s)? ____________________________________________________________________________

For official use only:
Centre number ________________________________
Young person identification number for this study ________________________________

Version 2 06/01/12
Appendix 5

Adolescent Relationship Questionnaire - A-RQ
(Henderson, 2010; based on Scharfe, 2009)

Not at all kind of very like me
like me like me like me
1 2 3 4 5 6 7

1. Please circle the letter A, B, C or D of the description that is most like you.

2. Below we have described 4 different ways that people act and feel when they are with other people. Please read each description and rate how much you are like each one when you are with people using the 7-point scale, ranging from "not at all like me" to "very like me".

<table>
<thead>
<tr>
<th>Description</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. It is easy for me to feel close to people. I feel okay asking people for help and I know that they will usually help me. When people ask me for help, they can count on me. I don't worry about being alone and I don't worry about others not liking me.</td>
<td></td>
</tr>
<tr>
<td>B. It is hard for me to feel close to people. I want to be close to people, but I find it hard to trust them. I find it hard to ask people for help. I worry that if I get too close to people they will end up hurting me.</td>
<td></td>
</tr>
<tr>
<td>C. I want to be really close to people, but they don't want to get that close to me. I am unhappy if I don't have people that I feel close to. I sometimes think that I care about people more than they care about me.</td>
<td></td>
</tr>
<tr>
<td>D. I don't care if I am close to people. It is very important for me not to ask for help, because I like to do things on my own. I don't like it if people ask me for help.</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 6

Adolescent Relationship Scales Questionnaire (A-RSQ)
(Henderson, 2010; based on Scharfe, 2009)

Think about all of the people in your life. Now read each of the following statements and rate how much it describes your feelings using the 7-point scale, ranging from "not at all like me" to "very like me".

Not at all like me  kind of like me  very like me
1               2               3               4               5               6               7

1. I find it hard to count on other people. Score

2. It is very important to me to feel independent. Score

3. I find it easy to get emotionally close to others. Score

4. I worry that I will be hurt if I become too close to others. Score

5. I am comfortable without close emotional relationships. Score

6. I want to be completely emotionally close with others. Score

7. I worry about being alone. Score

8. I am comfortable depending on other people. Score

9. I find it difficult to trust others completely. Score

10. I am comfortable having other people depend on me. Score

11. I worry that others don't value me as much as I value them. Score

12. It is very important for me to do things on my own. Score

13. I'd rather not have other people depend on me. Score

14. I am kind of uncomfortable being emotionally close to people. Score

15. I find that people don't want to get as close as I would like. Score

16. I prefer not to depend on people. Score

17. I worry about having people not accept me. Score
Appendix 7

The Self Image Profile
For Adolescents (SIP-A)

Richard J Butler

Name:               Age:

Sex:  Male / Female        Date:

Please read the instructions carefully. If you do not understand, ask for help.

1. First, please shade the box □ according to how you think you are using the 0 - 6 scale where, 0 means ‘not at all’ like the description and 6 means ‘very much’ like the description.

2. Then, put a star in the box * according to how you would like to be.

There are no right or wrong answers. Use any number along the scale to show how you think of yourself.

DO NOT WRITE BELOW LINE

<table>
<thead>
<tr>
<th>SI + ve</th>
<th>SUM OF ITEMS 1 - 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>SI + ve</td>
<td>SUM OF ITEMS 14 - 25</td>
</tr>
<tr>
<td>SD</td>
<td>SCORE ON ITEM 13</td>
</tr>
<tr>
<td>SE</td>
<td>SUM OF DISCREPANCY SCORES</td>
</tr>
</tbody>
</table>

130
<table>
<thead>
<tr>
<th></th>
<th>Kind</th>
<th>Happy</th>
<th>Friendly</th>
<th>Funny</th>
<th>Helpful</th>
<th>Hard Working</th>
<th>Talkative</th>
<th>Confident</th>
<th>Sporty</th>
<th>Intelligent</th>
<th>Fun to be With</th>
<th>Good Looking</th>
<th>Feel Different from Others</th>
<th>Lazy</th>
<th>Annoying</th>
<th>Moody</th>
<th>Mess About</th>
<th>Shy</th>
<th>Cheeky</th>
<th>Loud</th>
<th>Sarcastic / Bitchy</th>
<th>Worry a Lot</th>
<th>Bossy</th>
<th>Short Tempered</th>
<th>Get Bored</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Feelings are really important.

Your answers to the sentences over the page will help us understand how you feel.

Please read each of the sentences and put a tick [✓] beside the answer that describes you best.

Think about how you have been feeling over the last week, including today, when you read each sentence.

There are no right or wrong answers but it is important for you to let us know how you feel.

The sentence below is an example. Please put a tick in the box beside the answer that best describes you.

I like to play sports:

- [] Always
- [] A lot of the time
- [] Sometimes
- [] Not at all

Now turn over the page.
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel shaky or 'wound up'?</td>
<td>Always, A lot of the time, Sometimes, Not at all</td>
</tr>
<tr>
<td>I get a sort of frightened feeling as if something bad is about to happen</td>
<td>Always, A lot of the time, Sometimes, Not at all</td>
</tr>
<tr>
<td>I worry about things:</td>
<td>Always, A lot of the time, Sometimes, Not at all</td>
</tr>
<tr>
<td>I feel happy:</td>
<td>Always, A lot of the time, Sometimes, Not at all</td>
</tr>
<tr>
<td>I can chill out and feel relaxed:</td>
<td>Always, A lot of the time, Sometimes, Not at all</td>
</tr>
<tr>
<td>I feel sluggish / slowed down:</td>
<td>Always, A lot of the time, Sometimes, Not at all</td>
</tr>
<tr>
<td>I get a sort of frightened feeling like 'butterflies' in my tummy:</td>
<td>Always, A lot of the time, Sometimes, Not at all</td>
</tr>
</tbody>
</table>
PedsQL<sup>TM</sup>
Diabetes Module
Version 3.0

TEENAGERS REPORT (ages 13-18)

DIRECTIONS

Teenagers with diabetes sometimes have special problems. Please tell us how much of a problem each one has been for you during the past ONE month by circling:

0 if it is never a problem
1 if it is almost never a problem
2 if it is sometimes a problem
3 if it is often a problem
4 if it is almost always a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.
In the past ONE month, how much of a problem has this been for you...

### ABOUT MY DIABETES (problems with...)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel hungry</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. I feel thirsty</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. I have to go to the toilet too often</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. I have stomachaches</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. I have headaches</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. I go “low” or “hypo”</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. I feel tired</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. I get shaky</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. I get sweaty</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10. I have trouble sleeping at night</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>11. I get grumpy or annoyed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

### TREATMENT I (problems with...)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It hurts to prick my finger or give myself insulin injections</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. I am embarrassed about having diabetes</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. My parents and I argue about my diabetes care</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. It is hard for me to stick to my diabetes routine</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Whether you do these things on your own or with the help of your parents, please answer how hard these things were to do in the past ONE month.

### TREATMENT II - (problems with...)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It is hard for me to do blood glucose tests</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. It is hard for me to give myself insulin injections</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. It is hard for me to exercise</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. It is hard for me to follow a healthy diet</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. It is hard for me to wear my id bracelet/necklace or carry a card</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. It is hard for me to eat snacks between meals when I should</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

### WORRY (problems with...)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I worry about “going low” or “hypo”</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. I worry about whether or not my medical treatments are working</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. I worry about long-term problems from diabetes</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
In the past **ONE month**, how much of a **problem** has this been for you ...

<table>
<thead>
<tr>
<th>COMMUNICATION (problems with...)</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It is hard for me to tell the doctors and nurses how I feel</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. It is hard for me to ask the doctors and nurses questions</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. It is hard for me to explain my illness to other people</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Thank you for taking part in the study.
I would appreciate if you would answer the following questions as honestly as you can. There are no right or wrong answers. It would be useful to hear your opinion as to how the Sweet Text system was helpful or not.

How often did you receive the text messages?
Was it clear they were from Sweet Text? Yes/No (please circle as appropriate)
Were the messages understandable? Yes/No (please circle as appropriate)
How did the content make you feel?

To what extent do you think they helped you with your diabetes?

Were any of the messages unhelpful or annoying? If so, which ones?

Were any of the messages particularly helpful? If so, which ones?

Can you make any suggestions to improve Sweet Text that you think may help other young people who have diabetes?

Would you like to continue to receive messages that are similar to the ones in the study? Yes/No (please circle as appropriate)
Are there any other types of messages that you think you would find helpful?

Please let us know any other comments you would like to make about the study

Official use only:
Participant Identification number:
Site number:
Methodology Checklist 2: Controlled Trials

SIGN

Study identification *(Include author, title, year of publication, journal title, pages)*

<table>
<thead>
<tr>
<th>Guideline topic:</th>
<th>Key Question No:</th>
</tr>
</thead>
</table>

**Before completing this checklist, consider:**

1. Is the paper a **randomized controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: Reason for rejection: 1. Paper not relevant to key question ☐

2. Other reason ☐ (please specify):

**Checklist completed by:**

**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted RCT study...</th>
<th>In this study this criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Well covered Not addressed Adequately addressed Not reported Poorly addressed Not applicable</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised</td>
<td>Well covered Not addressed Adequately addressed Not reported Poorly addressed Not applicable</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used</td>
<td>Well covered Not addressed Adequately addressed Not reported Poorly addressed Not applicable</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation</td>
<td>Well covered Not addressed Adequately addressed Not reported Poorly addressed Not applicable</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial</td>
<td>Well covered Not addressed Adequately addressed Not reported Poorly addressed Not applicable</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation</td>
<td>Well covered Not addressed Adequately addressed Not reported Poorly addressed Not applicable</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way</td>
<td>Well covered Not addressed Adequately addressed Not reported Poorly addressed Not applicable</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td></td>
</tr>
</tbody>
</table>

143
### Appendix 13

<table>
<thead>
<tr>
<th>1.9</th>
<th>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</th>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
<td>Not reported</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### Section 2: Overall Assessment of the Study

<table>
<thead>
<tr>
<th>2.1</th>
<th>How well was the study done to minimise bias? Code ++, +, or –</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
</tr>
<tr>
<td>2.4</td>
<td>Notes. Summarise the authors conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question.</td>
</tr>
</tbody>
</table>
Methodology Checklist 3: Cohort studies

Study identification (Include author, title, year of publication, journal title, pages)

Guideline topic:

Key Question No:

Before completing this checklist, consider:

1. Is the paper really a cohort study? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question □ 2. Other reason □ (please specify):

Checklist completed by:

SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted cohort study:</th>
<th>In this study the criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Well covered Adequately addressed Poorly addressed Not addressed Not reported Not applicable</td>
</tr>
</tbody>
</table>

SELECTION OF SUBJECTS

<table>
<thead>
<tr>
<th>1.2 The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.</th>
<th>Well covered Adequately addressed Poorly addressed Not addressed Not reported Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3 The study indicates how many of the people asked to take part did so, in each of the groups being studied.</td>
<td>Well covered Adequately addressed Poorly addressed Not addressed Not reported Not applicable</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>1.4 The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.</td>
<td>Well covered Adequately addressed Poorly addressed Not addressed Not reported Not applicable</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>1.5 What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed.</td>
<td>Well covered Adequately addressed Poorly addressed Not addressed Not reported Not applicable</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>1.6 Comparison is made between full participants and those lost to follow up, by exposure status.</td>
<td>Well covered Adequately addressed Poorly addressed Not addressed Not reported Not applicable</td>
</tr>
</tbody>
</table>

ASSESSMENT

| 1.7 The outcomes are clearly defined. | Well covered Adequately addressed Poorly addressed Not addressed Not reported Not applicable |

Scottish Intercollegiate Guidelines Network. March 2004
### APPENDIX 13

<table>
<thead>
<tr>
<th>1.8</th>
<th>The assessment of outcome is made blind to exposure status.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Well covered</td>
</tr>
<tr>
<td></td>
<td>Adequately addressed</td>
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<td></td>
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<td>Not addressed</td>
</tr>
<tr>
<td></td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.9</th>
<th>Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Well covered</td>
</tr>
<tr>
<td></td>
<td>Adequately addressed</td>
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</tr>
<tr>
<td></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.10</th>
<th>The measure of assessment of exposure is reliable.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Well covered</td>
</tr>
<tr>
<td></td>
<td>Adequately addressed</td>
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<td>Not reported</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.11</th>
<th>Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Well covered</td>
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<tr>
<td></td>
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<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>1.12</th>
<th>Exposure level or prognostic factor is assessed more than once.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Well covered</td>
</tr>
<tr>
<td></td>
<td>Adequately addressed</td>
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</tbody>
</table>

### CONFOUNDING

<table>
<thead>
<tr>
<th>1.13</th>
<th>The main potential confounders are identified and taken into account in the design and analysis.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Well covered</td>
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<tr>
<td></td>
<td>Adequately addressed</td>
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<td>Not reported</td>
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<tr>
<td></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### STATISTICAL ANALYSIS

<table>
<thead>
<tr>
<th>1.14</th>
<th>Have confidence intervals been provided?</th>
</tr>
</thead>
</table>

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th>2.1</th>
<th>How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between exposure and effect? Code ++, +, or −</th>
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</table>

<table>
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<tr>
<th>2.2</th>
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