THE UNIVERSITY OF HULL

Development and Feasibility Testing of a Webpage-Based Diabetes Education in Adolescents with Type 1 Diabetes Mellitus in China

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ABSTRACT

Aim: This study aimed to develop a diabetes mellitus educational material specifically for 10-19-year adolescents with type 1 diabetes mellitus (T1DM) based on the health belief model, and to develop webpages for adolescents to study the material.

Background: More than 1.11 million children and adolescents (<20 years) worldwide were diagnosed with T1DM in 2019, which has increased by approximately 3% every year in the last few decades. China is fourth for prevalence of adolescents with T1DM. Suboptimal diabetes management causes acute and chronic complications, as well as psychosocial disorders. However, adolescents do not achieve optimal diabetes management of T1DM. Education is the key to successful diabetes management, which could also maximise the effectiveness of diabetes treatment and the advances in diabetes management and technology. Nevertheless, limited diabetes education resources are available and tested scientifically in China. Existing diabetes materials are difficult for adolescents to read because of medical terms without appropriate explanation. In addition, there are no diabetes educational materials specifically for children or adolescents.

Methods: A feasibility testing study was conducted to test if the research design was feasible, including the development of the type 1 diabetes educational material, the development of the webpages, selection and translation of the outcome scales, and recruitment and retention of participants.

Results: 1) The type 1 diabetes educational material was developed for adolescents aged 10-19 years, translated and assessed to have good readability by adolescents and good content validity by experts; 2) The webpages were developed and assessed by participants to have good to excellent usability; 3) A type 1 diabetes knowledge scale (T1DK) with 12 items was developed for adolescents. Another three scales already validated included self-efficacy, adherence and webpage usability. The four scales were translated and tested with good readability in adolescents and content validity in experts. 4) In this feasibility study, 16 adolescents registered the webpages and six completed fully.

Conclusion: It is feasible to develop type 1 diabetes educational material with good readability and content validity in China. The webpages were rated as good to excellent with respect to usability. Outcome scales had good readability and content validity. However, there was low feasibility at the data collection stage because of the lower recruitment and retention rates. Four strategies will be implemented to improve the recruitment and retention rates in future: involvement of patients' doctors or nurses; combination of several recruitment methods; regular and continuing contact with participants, and appropriate funding and incentives to participate.

In the future, a pilot with a large enough sample size will be conducted to test the new recruitment and retention strategies, and reliability and construct validity of the four scales. Subsequently, an effectiveness study will be conducted to test the effects of the web-based educational material on diabetes knowledge, self-efficacy and adherence among adolescents.

Key words: adolescents; type 1 diabetes mellitus; education; mobile; webpages; feasibility testing; diabetes knowledge; self-efficacy; adherence; webpage usability;

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PUBLICATIONS RELATED TO THIS STUDY

Zhao, X., Zheng, S., & Huang, H. (2017) A Systematic Review of Effect of Information Technology-based on Network and Mobile Phone on Blood Glucose Management in Children and Adolescents with Type1 Diabetes Mellitus. *Chinese Nursing Research*, 31(25), 3134-3140 (the Chinese systematic review in chapter 2)

Zhao, X., Ai, Z., Chen, Y., Wang, J., Zou, S., & Zheng, S. (2019). The Effectiveness of Parenting Interventions on Psychosocial Adjustment in Parents of Children and Adolescents with Type 1 Diabetes: A Meta-Analysis. *Worldviews on Evidence-Based Nursing*, *16*(6), 462-469

PROPOSED PUBLICATIONS

Zhao, X. L., Huang, H. Q., Zheng, S. L. Effectiveness of Internet and Smartphone-based Interventions on Diabetes Management of Children and Adolescents with Type 1 Diabetes: a Systematic Review (*Worldviews on Evidence-Based Nursing; Accepted on October 2020*) (Chapter 2 in this thesis)

Zhao, X. L., Hilton, A., Watson, R. Development and Validity Testing of a Type 1 Diabetes Educational Material for 10-19-year Adolescents (the target journals: *The Journal of Pediatric Nursing: Nursing Care of Children and Families*) (Chapter 5 in this thesis)

Zhao, X. L., Hilton, A., Watson, R. Development and Feasibility Testing of a Mobile Webpage-Based Diabetes Education in Adolescents (10-19 years) with Type 1 Diabetes Mellitus in China (the target journals: *Patient Education and Counseling*) (Main results in this thesis)

CHAPTER 1 INTRODUCTION TO THE STUDY

1.1. Diabetes mellitus is one of the largest international health emergencies in the 21st century

Blood glucose is the main source of energy in our body and comes from the food we eat. For healthy people, beta cells of the pancreas can make the hormone insulin to promote the absorption of glucose from blood to our cells to be used for energy. However, diabetes mellitus (DM) is a group of metabolic diseases, which is characterised by chronic hyperglycaemia resulting from defects in insulin secretion, insulin action, or both (Craig et al., 2009). According to the Diabetes UK and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), for people with DM, their pancreas cannot make any or enough insulin to transport glucose from blood to cells, or their bodies cannot respond fully to insulin (NIDDK, 2016, DiabetesUK, 2018), which means excess glucose remains circulating in the bloodstream.

Types of DM include type 1 Diabetes mellitus (T1DM), type 2 Diabetes mellitus (T2DM), gestational DM and other types of DM, among which T1DM and T2DM are more common internationally (DiabetesUK, 2018). In contrast to people with T2DM whose bodies do not make enough insulin or do not use insulin well, if someone is diagnosed with T1DM, it means their pancreas make none to very little insulin, and extra insulin needs to be injected every day to maintain health. According to the International Diabetes Federation (IDF), 7-12% of people have T1DM in high-income countries (IDF, 2015). T1DM is usually diagnosed in children and young adults, although it can appear at any age (NIDDK, 2016, DiabetesUK, 2018).

DM is one of the largest international health emergencies of the 21st century (IDF, 2017). According to the World Health Organisation (WHO), the global prevalence of DM in adults over 18 years nearly doubled, rising from 4.7% in 1980 to 8.5% in 2014

(WHO, 2016). In 2019, 463 million adults (20-79 years) were estimated to live with DM, which represented 9.3% of the worldwide population at this age group. This number is projected to reach 578 million by 2030 and 700 million by 2045 (IDF, 2019a). The IDF also predicted that, by 2045, a further 548 million people will be at high risk of developing DM because of impaired glucose tolerance (IDF, 2019b). DM has been diagnosed in every region of the world, and the top three regions of adults with DM are North America and Caribbean (13.3%), Middle East and North Africa (12.8%), and Western Pacific (9.6%) in 2019. The top three countries are China with 116.4 million adults with DM, India with 77 million and USA with 31 million in 2019. The largest increases of DM took place in those countries where the economy was moving from low to middle, including China (IDF, 2019a).

DM (including type 1 and type 2) is a disorder of metabolism of glucose, fat and protein, which results in the appearance of acute and chronic complications (WHO, 1999). The acute complications include hypoglycemia and ketoacidosis, which are potentially life-threatening. The chronic complications include retinopathy with potential blindness, nephropathy that may develop to renal failure, neuropathy with risk of foot ulcers, amputation, features of autonomic dysfunction, and increasing risk of cardiovascular, peripheral vascular, and cerebrovascular disease (IDF, 2015). These damages are irreversible. DM and its complications carry a heavy burden for any society, including disability, premature death and economic burden.

According to a meta-analysis involving of 26 studies in Europe, North America and Asia, between a 50-80% increased risk of disability was estimated among people with DM, compared with those without DM (Wong et al., 2013). In America, 40% of females and 25% of males with DM reported major mobility loss, a tenth of adults reported reduced instrumental activities of daily living (IADL) disability, and a quarter reported work disability (Gregg and Menke, 2016). For working-age adults (≤62 years old) with DM in USA, 12% of them were unemployed, 7% of employed participants had missed 5 days from work in the prior month, and 4% of employees reported severe difficulty with work (Korff et al., 2005). This was similar to the result of another national study in America, which reported a quarter of diabetic adults with work disability (Gregg and Menke, 2016).

DM was the seventh cause of death globally in 2016 (WHO, 2018c). According to the IDF, approximately 4.2 million adults died from DM and its complications in 2019, which was equivalent to a death every eight seconds (IDF, 2019b). The highest number of deaths caused by DM occurred in China, India, USA and Russian (WHO, 2016). DM and its complications also lead to premature deaths, which are considered preventable. According to the WHO, nearly half (46.6%) of deaths due to DM were in people under 60 years old in 2015, and 43% of deaths occurred before 70 years old in 2016 (WHO, 2016). Cardiovascular disease is one of the leading causes of death among adults with DM, which affected 32% of people with T2DM in high- and middle-income countries (Einarson et al., 2018, IDF, 2019b).

DM imposes a large economic burden on health care systems and national economies. Health care expenditure for people with DM (including type 1 and type 2) was two- to three-fold higher than for people without DM (IDF, 2017). In 2015, health spending on DM accounted for 11.6% of total health expenditure worldwide (IDF, 2015), which presented an 8% growth by 2017 (IDF, 2017), and 1.8% of global gross domestic product (GDP) (Bommer et al., 2018). Global health expenditure on DM was estimated to increase from USD 760 billion in 2019 to USD 845 billion in 2045. The top three countries with the highest diabetes-related spending were USA with USD 294.6 billion, China with USD 109.0 billion and Brazil with USD 52.3 billion (IDF, 2019a).

1.2. T1DM in children and adolescents

1.2.1. Defining child and adolescent

This study will only focus on "adolescents". However, articles regarding both children and adolescents will be reviewed because of inconsistent definitions of children and adolescents.

According to the Convention on the Rights of the Child issued by the Office of the United Nations High Commissioner for Human Rights (OHCHR) in 1989, a child means every human being below the age of 18 years (OHCHR, 1989). As mentioned by the Child Development Institute (CDI), childhood is divided into infant (0-2 years), preschool (2-5 years), school age (5-12 years) and teenager (13-18 years) (CDI, 2018), which is similar to the categories from the American Academy of Paediatrics (AAP, 2018). In China, age limits of children and adolescents are also ambiguous. Under the Minors Protection Law, the term "minors" refers to citizens who are younger than 18 years old in China (ChinaGov, 2006). In China's hospital system, a patient who is no more than 14 years old needs to see a doctor in a pediatric department (Liu et al., 2018). According to the World Health Organisation (WHO), adolescents are young people who are between the ages of 10 and 19 years (WHO, 2018a), which will be regarded as the criteria of the age limit of adolescent in this study.

1.2.2. High morbidity of children and adolescents with T1DM

Although T2DM in children and adolescents has been increasing because of lifestyle change and increasing obesity (IDF, 2017), T1DM is still predominant among children and adolescents with DM (IDF, 2019b), which is the main reason why this study only focuses on children and adolescents with T1DM.

A systematic review (Chen et al., 2017) including 87 studies in 72 countries indicated the overall incidence of childhood (<20 years) T1DM from 1965 to 2012 was 11.43/100,000 children/year worldwide. The highest incidence of childhood T1DM was in North America, 21.75/100,000 children/year, followed by Europe 13.93/100,000 children/year, Africa 7.38/13.93/100,000 children/year, and Asia 4.31/100,000 children/year (Chen et al., 2017). According to the International Diabetes Federation, children and adolescents (<20 years) with T1DM increased by around 3% every year (IDF, 2019b). Similarly, a study from 26 centres representing 22 European countries estimated the annual growth rate of childhood T1DM (0-14 years) was 3.4% from 1989 to 2013 in Europe, although a temporary slowing (annual increase of 1.1%) presented in 2004-2008 (Patterson et al., 2019). Another survey covering 61 million commercially insured Americans reported that the incidence rate of T1DM in adolescents (0-19 years) increased by 1.9% annually from 2001 to 2015 in USA (Rogers et al., 2017). Totally, it was estimated more than 1.11 million children and adolescents younger than 20 years old had T1DM globally in 2019 (IDF, 2019b). European region, North America and Caribbean region, and Middle East and North Africa region were estimated to be top three regions for number of children and adolescents (<20 years) with T1DM (IDF, 2017). The top five countries with the highest number of children and adolescents (<20 years) with T1DM were USA, India, Brazil, China and Russia (IDF, 2017).

According to the standard diagnostic criteria proposed by the IDF and WHO, China was estimated to have approximately 54,000 children and adolescents (<20 years) with T1DM in 2019. This number accounted for nearly half of the Western Pacific region (IDF, 2019b). However, based on HbA1c levels, a study estimated that 1.7 million Chinese adolescents had diabetes by 2009, which covered 228 communities and approximately 56% of China's population. This indicated a diabetes rate of 0.9% in adolescent at the age of 7-17 years in China (Yan et al., 2012). The great differences may be raised by different diagnostic criteria and sampling methods. This was also associated with the deficiency of a nationwide diabetes registry in China to provide accurate epidemiological data (Sun et al., 2017). However, the incidence rate of T1DM in Chinese children and adolescents has increased in recent decades. Between 1988 to 1996, the incidence rate of T1DM in children (<15 years) was 0.52/100,000 person-years for boys and 0.66/100,000 for girls, according to the statistics from the WHO DiaMond Project China Participating Centre and the Chinese Academy of Preventive Medicine (CAPM) which covered a population of approximately 24 million children (Li et al., 2000). During 2010-2013, data from 505 hospitals in 13 cities revealed the estimated incidence of T1DM was 1.93/100,000 in children aged between 0-14 years (Weng et al., 2018). Another study also reported the prevalence of T1DM (per 100,000 persons) in adolescents (0-18 years) increased from 90.9 in 1995-2000 to 101.4 in 2005-2010 through a follow-up of 14 Chinese medical centres for 15 years (Fu et al., 2013).

The incidence rates of T1DM in children and adolescents vary across different areas of China. In Harbin, a northeast city in China, the annual incidence rate was reported to be 0.73/100,000 person-years in children aged 0-14years from 1990-2000 (Zhang et al., 2008), which was lower than that in Shanghai, a city in the middle of China's east coast. The annual incidence of children (0-14 years) was 3.1 per 100,000 person-years from 1997-2011 in Shanghai (Zhao et al., 2014). In Chengdu, a city in the southwest of China, the incidence rate of T1DM in children (0-14 years) was reported to be 1.14 per 100,000 person-years from 2010-2013 (Weng et al., 2018). However, population-based epidemiology surveys are still needed to ascertain the incidence rate of children and adolescents with T1DM in different areas and cities in China because of its vast territory and varying dietary habits. Furthermore, compared with those aged 0-4 and 5-9-year age groups in China, children and adolescents from 10-14 and 15-19-year age groups had a greater risk of developing T1DM with the incidence rate of 6.58 and 5.39 per 100,000 person-years (Wu et al., 2016), which was consistent to the results in USA (Dabelea et al., 2014), UK (Hsia et al., 2009), Ireland (Roche et al., 2016) and Netherland (Fazeli Farsani et al., 2016).

1.2.3. Responsibility changing from parents to children

T1DM is a lifelong and progressive health condition, which cannot be cured and needs continuous care. Diabetes management is difficult for patients at any age because they are faced with many important changes in daily life, such as insulin injection and adjustment, diet adjustment, blood glucose monitoring, hypoglycemia, and frequent clinic attendance (Wyckoff et al., 2015). However, physical growth, cognitive development and psychological characteristics, such as adjustment, make it particularly challenging for children and adolescents to manage DM (Halvorson et al., 2005). Poor adherence to therapy is a common concern in children and adolescents with DM (Datye et al., 2015). In addition, some children and adolescents are not ready to accept the change of responsibility, or have lower self-efficacy for DM management (Kaugars et al., 2011). Limited knowledge and skills were also reported among them to deal with DM (Olsen Roper et al., 2009, Martin et al., 2017).

Therefore, families play an important role in DM management among children and young adolescents. A systematic review indicated family involvement was an important predictive factor for glycaemic control in younger adolescents (Tsiouli et al., 2013). However, as children grow older, their requests for autonomy and independence become stronger (Mellin, 2004). In addition, adolescents' complicated and busy life away from home poses difficulties for DM management (Mellin, 2004). It is a time to transfer the primary responsibility of DM care from parents to adolescents themselves. In the process of responsibility transformation, the roles of children and parents also need to alter. If not, some diabetes-related conflicts and disagreement occur between children and parents (Weinger et al., 2001). Family conflict was presented to be adversely related to children's glycaemic control (Tsiouli et al., 2013).

1.2.4. Suboptimal glycaemic control in children and adolescents with T1DM

DM management in children and adolescents is never easy because of physical growth and insulin resistance (IR). Adolescents with T1DM and a family history of T2DM are reported to be more likely to develop IR if they gain excessive body weight (Pozzilli et al., 2011). Tanner staging is an objective classification system to track the development of children during puberty (Emmanuel and Bokor, 2019). IR begins to increase significantly by Tanner stage 2 (T2) (10-11.5years), remains constant between T2 and T4 (13-15years), and returns almost to T1 (<10years) levels by the end of puberty T5 (>15years) (Moran et al., 1999).

HbA1c is the key measure of glycaemic control for people with DM. According to the International Society for Paediatric and Adolescent Diabetes (ISPAD) Clinical Practice Consensus Guidelines 2018, the target of HbA1c has been recommended to be <7.0% (53 mmol/mol) in children and adolescents with DM (DiMeglio et al., 2018). However, a meta-analysis with 19 studies including 2397 adolescents (<19 years) with T1DM from 1950-2008 reported ranged A1c means from 6.6% to 11.4% with the average A1c value of 9.0% (Hood et al., 2009). In 2013-2014, a cross-sectional survey across 528 diabetes centres of eight high-income countries, including Germany, England, Wales, and USA, showed the lowest mean HbA1c of 7.6% in Sweden and the highest mean HbA1c of 8.8% in Wales (Charalampopoulos et al., 2018). In this survey, the mean HbA1c value was 8.7% in USA (Charalampopoulos et al., 2018), which was similar to the result (M, 8.6%) of another American study (Al Sawah et al., 2016). In Australia, the national median HbA1c level was 8.3% in children and adolescents (≤18 years) with

T1DM, and only 27% had HbA1c levels less than 7.5% (Phelan et al., 2018), which was the old HbA1c target from the IDF (IDF, 2015, IDF, 2017). A national cohort study in Bulgaria presented a mean HbA1c level of 8.42% in 2014 among children and adolescents (0-19 years) with T1DM (Archinkova et al., 2017). In Saudi Arabia, the mean HbA1c was 9.6% in children and adolescents with T1DM (Al Zahrani and Al Shaikh, 2019).

A cross-sectional study including children (<18 years) from 96 pediatric diabetes centres in Asia and the Western Pacific Region showed that the mean HbA1c among children with T1DM was highest in Indonesia (10.6 ± 2.7%) and lowest in Australia (7.8 ± 1.2%). The mean HbA1c among Chinese children with T1DM was 9.5 ± 1.9% in Mainland China, which was higher than Hong Kong (8.6 ± 1.6%) and Taiwan (8.9 ± 1.6%) (Craig et al., 2007). However, the sampling methods and representativeness of samples need to be questioned because only two diabetes centres in Mainland China were included in the study, nine in Hong Kong, and twelve in Taiwan. A survey from 14 major cities of Hunan Province which is situated in central southern mainland China reported that the mean HbA1c was 9.68% in younger people aged 8-19 years with T1DM, and 8.80% in school-aged children (8-12 years) and 10.31% in adolescents (13-19 years) (Guo et al., 2013).

1.2.5. Complications and the influences on children and adolescents with T1DM

If blood glucose cannot be controlled well in children and adolescents, eventually, different kinds of acute and chronic complications occur. Hypoglycaemia and diabetic ketoacidosis (DKA) are two of the most common acute complications. In a systematic review, the incidence of severe hypoglycemia still ranged from 1.21 to 30 per 100 patient-years among children (<18 years) with T1DM in 2011-2016 across the world (Cherubini et al., 2019). In New South Wales (NSW) and the Australian Capital

Territory (ACT), the incidence of at least one episode of severe hypoglycaemia in the previous three months was 6.7% among adolescents with T1DM (Craig et al., 2002), which was 11.2% in Asia and the Western Pacific Region (Craig et al., 2007). Diabetic ketoacidosis (DKA) is also a potentially life-threatening condition, which is caused by a high level of ketones in the blood when the body is lacking insulin and the fat is broken down. A systematic review synthesised the data from 31 countries and showed that the frequency of DKA at diagnosis among children with T1DM ranged from 12.8% in Sweden to 80% in the United Arab Emirates (Usher-Smith et al., 2012). A 41.9% prevalence of DKA were reported in China, but the data were not representative because the data included was from only one hospital in Shenyang (a north city) (Xin et al., 2010, Usher-Smith et al., 2012). Two peaks of DKA occur in children aged 0-5 years (33.9%) and 10-12 years (34%), which may be related to aggressive β cell damage and the onset of puberty respectively (Szypowska et al., 2017). However, another study reported that DKA frequently occur in adolescents (12-15 years) with T1DM because they have higher HbA1c level and high insulin dose per kilogram (Craig et al., 2007).

Chronic complications are correlated with diabetes duration (Walsh et al., 2006, Goni et al., 2016). A cohort in Spain reported the incidence of nephropathy was 2.6% in patients with T1DM at 5 years since onset, which increased to 6.3% at 10 years and 11.9% at 15 years (Goni et al., 2016). The WHO DiaMond study group conducted a survey to explore T1DM complications in 22 centres of 17 countries. Central European countries exhibited high rates of retinopathy (31.6% in Lithuania, 24.2% in Romania) and neuropathy (29.9% in Lithuania, 12.4% in Romania) in childhood-onset T1DM after a short duration of diabetes (5-15 years). Around 7.3% retinopathy and 2.5% neuropathy were reported among Chinese patients with T1DM in the short-duration group (5-15 years) (Walsh et al., 2006). However, childhood-onset T1DM was found to be a protective factor of diabetes complications (Svensson et al., 2004, Raile et al., 2007). A national German survey indicated that young age (<5 years) at diagnosis of T1DM reduced the risk of microalbuminuria, which is an early marker of diabetic nephropathy (Raile et al., 2007). Another study in Sweden presented that onset of T1DM before the age of 5 years prolongs the time to develop background retinopathy, which is an early stage of retinal damage, compared with the 5-11 and >11-year-age groups (Svensson et al., 2004).

Diabetes also had a negative impact on physical and cognitive growth, and life expectancy. The impaired prepubertal and pubertal growth in children and adolescents with T1DM, such as near-adult height and peak height velocity, was mainly affected by suboptimal glycaemic control and adopted insulin regime (Bonfig et al., 2012, Giannini et al., 2014). A history of severe hypoglycemia was associated with the change of regional brain functions (Perantie et al., 2007). Furthermore, a meta-analysis showed that children (<18 years) with TIDM performed slightly less well on intelligence tests and some specific neuropsychological skills than those who had no diabetes (Gaudieri et al., 2008). The children with earlier DM onset, before 7 years old, showed greatest cognitive disruption (Gaudieri et al., 2008, MacLeod et al., 2017). In addition, the life expectancy of people with T1DM was reduced approximately 11 years for men and 13 years for women, respectively, compared with those without DM (Livingstone et al., 2015).

1.2.6. Psychosocial issues resulting from diabetes in children and adolescents

In addition to suboptimal blood glucose control and complications, children and adolescents also experienced different degrees of psychological issues. A meta-analysis indicated that children with diabetes were more likely to experience psychological difficulties than their peers without diabetes, including depression, anxiety and distress

(Reynolds and Helgeson, 2011). From their perspectives, school children felt they were different from their peers (Guthrie et al., 2003), and adolescents described their situation as hard (Woodgate, 1998). In addition, a qualitative meta-synthesis reported that uncontrolled blood glucose also made patients with T1DM feel irritable, hopeless and vulnerable, which were closely associated with problems in relationship, self-image and confidence (Vanstone et al., 2015).

Diabetes in children and adolescents also brings a heavy economic burden to families and countries in some regions of this world. For a family in urban Sudan, 65% of the family expenditure on health was used for the diabetic child. The median annual expenditure of DM care was USD 283 per child with T1DM, 36% of which was spent on insulin (Elrayah et al., 2005). In Spain, the mean annual cost of adolescents with T1DM was €27,274, among which familial care accounted for 83%, followed by medical materials (8%), outpatient and primary care visits (3.1%) and insulin (2.1%) (Lopez-Bastida et al., 2017). Compared with pediatric patients with T1DM whose HbA1c<7.5% (58 mmol/mol) without complications (€3636), those whose HbA1c≥7.5% (€4704) or with complications (€5713) costed more (Lopez-Bastida et al., 2017). China had the second highest healthcare expenditure on patients (20-79 years) with DM, however, there has been no report about expenditure in Chinese children and adolescents with T1DM (IDF, 2019a).

1.3. Education contributes to successful diabetes management

Evidence shows that educational interventions had small to medium beneficial effectiveness on blood glucose in children and adolescents with DM (Hampson et al., 2001, Rosenbauer et al., 2012, Grey et al., 2013). Another integrated review also reported modest improvements in diabetes knowledge, skills and behaviours, however, the improvements were often not sustained, which would suggest a need for continuous education intervention (Gage et al., 2004). Although there was no evidence that education can significantly reduce short-term or long-term diabetes complications, it was found to reduce health service utilisation (Couch et al., 2008). In addition, most studies in an integrated systematic review reported diabetes education was associated with reduced cost, cost saving, cost-effectiveness, or a positive return on investment (Boren et al., 2009).

According to the ISPAD Clinical Practice Consensus Guidelines, education has been regarded as the key to successful diabetes management, which could maximise the effects of diabetes treatment and the advances in diabetes management and technology (Phelan et al., 2018). Every child or adolescent with DM is recommended to receive quality assured structured education (DiMeglio et al., 2018). The American Diabetes Association (ADA) also recommends that adolescents with T1DM should receive culturally sensitive, developmentally appropriate, and individualised diabetes management education (ADA, 2020).

1.4. Current state of diabetes education and management in western countries

In some western countries, such as the UK and USA, diabetes education has been accepted as the core of diabetes management. Diabetes self-management education has developed into a structured, ongoing, patient-centred and collaborative process to support patients with DM to integrate self-management into their daily life (Chatterjee et al., 2018).

1.4.1. Diabetes education and management state in UK

- A three-level diabetes self-management education system

A three-level diabetes self-management education has been conducted in UK. Level one is one-to-one advice from health care professionals. Level two refers to typically less formal and more flexible education programmes to support ongoing learning, such as face-to-face group-based education (maybe a single one- or two-hour session), peer-based programmes, or technology and internet-based approaches (Wenzel, 2016). Level three is used to describe the structured education programmes which meet nationally-agreed criteria defined by the National Collaborating Centre for Women's and Children's Health (NCC-WCH), including evidence-based curricula, trained educators, quality assurance of teaching standards and regular audit (NCC-WCH, 2015, NCC-WCH, 2016). Some national structured diabetes education programmes are available for people with DM in the UK and have been assessed to be effective in the studies, such as DAFNE (Dose Adjustment For Normal Eating) for adults with T1DM (Hopkins et al., 2012), DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) for adults with T2DM (Davies et al., 2008), and X-PERT (Patient-centred, Group-based Self-Management Programme) for people with T1DM and T2DM, as well as those at risk of diabetes (Deakin et al., 2006).

- An evidence-based diabetes management and education guideline for children and young people

In 2015, an evidence-based guideline was developed for children and young people with type 1 and type 2 diabetes by the National Collaborating Centre for Women's and Children's Health (NCC-WCH), which summarised existing evidence and provided recommendations about diabetes management and education (NCC-WCH, 2015). The guideline recommended the universal principles for diabetes education in children and young people:

1) Persons with DM should be included in the education process.

2) Diabetes educators should clearly understand the special and changing needs of children, young people and their families as they grow through different stages of life.

3) Educators, including doctors, nurses, dieticians and other healthcare professionals, should have access to continuing specialised training about diabetes education and educational methods.

4) Diabetes education should be based on a thorough assessment of the children's attitudes, beliefs, learning style, ability and readiness to learn, existing knowledge and life goals.

5) Diabetes education needs to be personalised and appropriate to each individual's age, stage of diabetes, maturity, lifestyle and cultural difference.

6) Diabetes education needs to be continuous and repeated for it to be effective. Diabetes education should be planned, documented, monitored and evaluated regularly.

- The diabetes management and education team, competencies and training

In addition, the Diabetes Multidisciplinary Team (DMT) plays an important part in diabetes management and education, which consists of diabetologists, inpatient diabetes specialist nurses (DSNs), community DSNs, dietitians, podiatrists and ophthalmologists. The DSNs have a specialist qualification in diabetes and play a central role in diabetes education of children, families and other health care professionals (Cable, 2016).

Some national competency frameworks have been developed for the diabetes multidisciplinary team to highlight core nursing skills and competencies in diabetes care, such as "An Integrated Career and Competency Framework for Diabetes Nursing" (TREND-UK, 2015), "An Integrated Career and Competency Framework for Dietitians and Frontline Staff" (Deakin and Group., 2011). In addition, some short and online courses are available for healthcare professionals to improve diabetes care and education at Diabetes UK, as well as master or postgraduate diabetes courses in some universities. For example, the Cambridge diabetes education programme (CDEP) is an online diabetes competency-based training for all levels of healthcare practitioners, which is accredited and endorsed by Diabetes UK, the British Dietetics Association and the Cambridge University Health Partnership (CDEP, 2020).

- Structured diabetes education programmes for children and adolescents

Some structured diabetes education programmes have been developed for children and adolescents with T1DM in UK. For example, the KICk-OFF (the Kids In Control OF Food) programme is a 5-day group education course in adolescents with T1DM, which focuses on carbohydrate counting, insulin adjustment, and management of hypoglycaemia, ketosis and long-term complications (Price et al., 2013, Price et al., 2016). The CASCADE (Child and Adolescent Structured Competencies Approach to Diabetes Education) intervention is a manual-based four-module structured education programme, which uses motivational approaches to encourage and enhance behaviour change in children and adolescents with T1DM (Christie et al., 2016).

1.4.2. Diabetes education and management state in USA

- A defined internal structure

In America, diabetes self-management education and support (DSMES) is the cornerstone of care for all individuals with DM to achieve satisfied health-related outcomes, which is also an ongoing process of promoting knowledge, skill, and ability necessary for diabetes self-management (Powers et al., 2017). The national standards for DSMES were updated in 2017 to define quality diabetes self-management education and to assist diabetes educators in diverse settings to provide evidence-based diabetes education (Beck et al., 2017).

- A multifaceted education team with certification

According to the national standards in 2002, a multifaceted education instructional team should consist of a Registered Nurse, Registered Dietitian, physician, exercise physiologist, behaviourist, ophthalmologist, optometrist, pharmacist, podiatrist, other health care professionals, and paraprofessionals (Mensing et al., 2002). The instructional team must include at least a Registered Dietitian, a Registered Nurse, or a pharmacist with training of DSMES, or other health care professionals with certification as a Certified Diabetes Care and Education Specialist (CDCES) or Board Certification in Advanced Diabetes Management (BC-ADM) (Beck et al., 2017).

According to the American Association and Diabetes Educators, the three levels of diabetes educator providers were revised to achieve better diabetes care in 2016. Level 1 educators (Beginner/Advanced Beginner) are healthcare providers who provide patients with the essential knowledge and skills needed for diabetes self-care. Level 2 educators (Competent/Proficient Intermediate) are the providers who have achieved an advanced knowledge and skills related to diabetes management and education. Level 3 educators (Expert/Advanced) are advanced experts in diabetes management, education, and research. In addition, health navigators, health workers, pharmacy technicians, medical assistants, and others assists in the DSME programmes were approved as diabetes paraprofessionals at two levels. Level 1 diabetes paraprofessionals are complementary workers who have various roles in the information dissemination, acquisition of baseline skills and provision of self-management support. Level 2 diabetes paraprofessionals are complementary healthcare workers to play a defined role in a certified or recognised diabetes education or prevention programme (AADE, 2017).

- Population evaluation and individualisation

The community and regional demographics, such as ethnic or cultural background, sex, age, formal education levels, literacy, numeracy, and perception of diabetes risk and complications, need to be evaluated to determine the DSMES services. In addition, the DSMES services must be patient-centred, in cooperation of patients, and focus on patients' priorities and values (Beck et al., 2017, Haas et al., 2012).

- Evidence-based curriculum and outcomes evaluation

The DSMES curricula must be up-to-date, evidence-based and flexible. The providers of the DSMES services should assess the effects of the educational services and if participants are achieving their personal self-management goals. Furthermore, ongoing support should be available for participants, as well as resources or activities which best suit their diabetes self-management needs. A DSMES services quality coordinator will evaluate the effects of the DSMES services and identify the areas for improvement through a systematic process and outcome assessment (Beck et al., 2017, Haas et al., 2012).

- Diabetes care and education guidelines for children and adolescents

In addition, some guidelines were developed specifically for diabetes care and education in children and adolescents with DM in USA, including Diabetes Care for Emerging Adults: Recommendations for Transition From Pediatric to Adult Diabetes Care Systems (Peters et al., 2011), and Children and Adolescents: Standards of Medical Care in Diabetes-2020 (ADA, 2020).

1.5. Current state and influencing factors of diabetes education and management in China

However, there still has been a big gap between the western countries and China in diabetes education and management.

1.5.1. Current state of diabetes education and management in China

First, the awareness of DM management and education are still relatively low in China (Wilson and Gyi, 2010, Lou et al., 2011), especially in the rural areas (Wang et al., 2018). Patients have not recognised the central role of education in diabetes self-management. Education is treated as an optional supplement to medical treatment (Choi et al., 2017).

Second, although guidelines were developed to help doctors diagnose and treat DM in children and adolescents, there are no guidelines or standards regarding diabetes education, such as standards of DM education training, training and certification of diabetes educators, and strategies to assess diabetes education programmes (Wilson and Gyi, 2010).

Third, nurses and physicians often play important roles in diabetes care and education in China, and little multidisciplinary care or education is observed (Choi et al., 2017). In addition, there is no available system to become certificated diabetes educators because there are no formalised and standardised diabetes education training programmes and examinations in China (Lou et al., 2011).

Fourth, nurses and physicians often decide the amount and types of information given to person with DM, rather than based on patients' understanding and experiences in China (Wilson and Gyi, 2010). Diabetes care and education are delivered through top-down didactic teaching with few strategies to encourage audiences' participation. There were no national and validated diabetes educational materials specifically for children or adolescents with diabetes. Deficit of easy-to-use diabetes materials or brochures is considered by physicians to affect patients' diabetes control (Choi et al., 2017).

Furthermore, a study reported that 60% of patients with T1DM did not receive any education in the past 12 months. Most of those who received education just attended education sessions once in Beijing and Shantou, a coastal city in Guangdong Province (McGuire et al., 2017). Some patients are only given printed materials for self-study (Zhao et al., 2013).

1.5.2. Influencing factors for diabetes management and education in China

(1) China's healthcare policy and related challenges

A systematic review presented that the healthcare system had an effect on patients' diabetes treatment and management (Ong et al., 2018). Not having health insurance was also reported to affect the processes and outcomes of diabetes care (Bowker et al., 2004).

Different from the National Health Service (NHS) UK which provides comprehensive, universal and free services to residents in the UK (NHS, 2015), Chinese medical insurance plays an irreplaceable role in Chinese healthcare system, which is a cost-based, fee-for-service system. However, according to the National Medical Security Administration (NMSA), public medical insurance has reached over 95% of the Chinese population by 2018, including children and adolescents (NMSA, 2019). The public medical insurance consists of urban employee insurance, urban resident insurance and rural resident insurance (Li et al., 2017). When it comes to cost-sharing and out-of-pocket spending, inpatient and outpatient care are subject to different deductibles, copayment, and reimbursement ceilings in the three different kinds of public medical insurance. For example, for adolescents or students in China, their parents together with the government would buy the medical insurance for them. Once they are diagnosed with DM, they can get approximately 70-75% reimbursement for inpatient care and 50% for outpatient care (Sun et al., 2017). One study indicated participating in the medical insurance significantly increased children's annual hospital visit frequency, especially for children who come from rural China (Guan and Tena, 2018).

In addition to the public medical insurance, the Chinese government also managed to establish a multi-level medical security system to protect the basic medical right of the poor and vulnerable people, including the urban and rural medical assistance policy, first aid medical assistance policy, and catastrophic disease medical assistance policy, according to the National Health Commission (NHC) (NHC, 2017, NHC, 2013). Furthermore, commercial health insurance has also been promoted in recent decades and plays an essential part in reducing health burden in China (Choi et al., 2018).

Although substantial progress was made to provide all people with equal access to basic healthcare in the past 10 years through health-care reform in China (Yip et al., 2019), several factors and challenges still exist in the Chinese health system to affect diabetes management and education.

- Medical insurance coverage

There are still 5% of population without the coverage of public medical insurance. Although certain medications treating DM, including insulin, have been involved in the public medical insurance, out-of-pocket fee payment is still expensive for some families, especially those in poverty. However, the application of medical assistance is a complicated process, which needs to be simplified to ensure that the poor can be treated appropriately and quickly. In addition, Shanghai is one of several cities with the involvement of insulin pen needles in the local medical insurance (rsj.sh.gov, 2018). Neither glucose meters, glucose strips, nor insulin pump are covered, which also lead to substantial costs for patients (Shen et al., 2013). One study indicated that lack of insurance coverage for self-monitoring testing supplies was significantly associated with higher HbA1c (Bowker et al., 2004).

- Demands on health professionals exceed supply

According to statistics from the World Bank, the number of Registered Nurses and Midwives per thousand population was 2.342 in China in 2015, however, this number was 8.582 in the European Union and 8.827 in the UK. Physicians per 1000 people was 1.785 in China, 3.847 in the European Union and 2.778 in the UK by 2015 (Worldbank, 2019).

Patient-to-nurse/doctor ratio or workloads is one of risk factors for working burnout (Huang, 2016, Lo et al., 2018). Data from 108 Chinese hospital showed nearly half of nurses were reported to have high levels of burnout (Zhang et al., 2014), and burnout among doctors in China was reported to range from 66.5% to 87.8% in a systematic review (Lo et al., 2018). Doctors and nurses in the Chinese hospitals feel overwhelmed when finishing daily treatment or medical advices, and do not have enough time to provide systematical education for patients (Lo et al., 2018, Wang et al., 2020).

- Imbalanced health and information resources

Imbalanced resource between hospitals and communities is a common issue. Compared with western countries, medical resources in the community are limited in China. A few not-for-profit organisations are involved in DM advocacy and education. DM education resources in the community are limited, including financial investment, technical and human resources (Zhao et al., 2013).

Imbalanced resource between urban areas and rural areas also exists in China. For example, village doctors in rural areas receive less professional and continuing education, and have a so-called village doctor certificate, rather than a regular license (Li et al., 2017). It is more difficult for children and adolescents with DM in rural areas to attend regular clinic visit or get updated information about DM (Guo et al., 2012).

(2) Cuisine culture and related challenges

In China, food plays a very prominent part in people's life. It takes, on average, 1-2 hours to make a meal, and from 20 minutes to several hours to eat. Food is not only the source of nutrition, but also plays an irreplaceable role in sociality to establish and maintain relationship with others. Several challenges exist in Chinese cuisine culture to affect diabetes management and education.

- Different from Western people eating food from their own plate, Chinese people prefer to share food with others at a table. Therefore, it is not easy to count and control energy intake (Ma, 2015).
- Moreover, over the past two decades, with the development of economy and increasing western fast foods, processed foods and snacks, excess energy and fat intake lead to increasing obesity, including among children and adolescents (Xu et al., 2015).
- The frequency of shared family meals was found to be significantly related to healthy dietary pattern and a normal weight range in children and adolescents (Hammons and Fiese, 2011). However, takeaway food consumption has become extremely popular among Chinese adolescents because of its convenience and development of online payment system (Liu & Chen, 2019).

1.6. Importance of electronic health (eHealth) technologies in diabetes education and management

The increasing incidence of diabetes, suboptimal blood glucose control, and increasing need for psychological support among patients pose a challenge for traditional diabetes management and education, which require the development of new approaches to expand access to diabetes care and education, improve efficiency of diabetes care, and reduce financial burden on countries (Papaspurou et al., 2015).

Electronic health (eHealth) is defined as “the use of information and communication technologies for health” by the World Health Organisation (WHO, 2017). According to the report of the third global survey on eHealth published by the WHO, delivery of healthcare system with information technologies has become mainstream worldwide (WHO, 2017). eHealth is potentially cost-effective and efficient in support of health by using information communication technologies (Sanyal et al., 2018). eHealth technologies are widely used to support diabetes care and education, including websites, mobile apps, telemedicine, social media, video games, wearable technologies and artificial intelligence system (Rollo et al., 2016). The effectiveness of eHealth education on HbA1c was considered comparable to traditional diabetes education among patients with type 1 diabetes in a systematic review (Feigerlová et al., 2020).

Mobile health (mHealth) is a subset of eHealth, which was described as the use of mobile devices for health improvement (WHO, 2017). With the popularity of mobile technologies, mHealth interventions in diabetes expanded to automatic text messaging, wearable blood glucose meters, insulin management apps and virtual health coaching (Shan et al., 2019). A systematic review indicated that mHealth would be beneficial in glycaemic control among patients with T1DM (Wang et al., 2019), as well as communication between adolescents and healthcare providers (Sinisterra et al., 2020).

CHAPTER 2 LITERATURE REVIEW

This chapter consists of three parts:

1) Comparing the effects of traditional education methods on T1DM management in children and adolescents;

2) Summarising the effects of internet-based education on T1DM management in children and adolescents based on the published paper (Zhao et al., 2017) in Appendix1;

3) Summarising the purpose of the current study;

2.1. A review of traditional education methods and the effects on T1DM management in adolescents

Appropriate education methods play an essential role in T1DM management and education. Before the development of internet, traditional education delivery methods in this review mainly referred to face-to-face, written material (printed material or booklet), games and videos which needed no access to the internet, phone or computer. This section summarises the effects of the traditional education methods on diabetes management among children and adolescents with T1DM.

2.1.1. Method

(1) Search strategy

Cochrane library, Pubmed, Embase and Web of Science were searched from 1990 to March 2020. The Cochrane library is a database of systematic review and meta-analysis, which was checked to see if there were any existing systematic reviews on this topic. Pubmed contains 24 million citations about medicine, nursing and health care systems, which is freely available on the internet. Embase is more comprehensive than Medline, which includes all the citations in Medline plus 6 million more. Web of Science is a multidisciplinary research platform which enables simultaneous cross-searching of a range of citation indexes and databases.

The search strategy used as follows: "*Type 1 diabetes and (child* or kid or adolescent or juvenile or teen* or youth) and (education or 'written material' or 'printed material' or face-to-face or booklet or game or video)".* The truncations make it possible to search different forms of a word simultaneously and increase the search results. Reference lists of publications were searched for potential articles.

(2) Inclusion criteria and exclusion criteria

Inclusion criteria:

- The target population was children or adolescents with T1DM. Studies explored the effects of diabetes education. Education methods included face-to-face, written material (printed material or booklet), game or video. Articles were published in English;

Exclusion criteria:

- Gestational diabetes, type 2 diabetes, non-intervention studies, or studies about DM prevention, protocol, conference abstract, and surveys were excluded. Studies with the involvement of internet or smartphone were also excluded.

2.1.2. Result

Of 265 abstracts originally screened, 123 papers were found to be duplicates. After reading titles and abstracts, 73 were excluded because of being irrelevant to this topic. Sixty-nine met the initial inclusion criteria for further assessment, after reading full articles, 46 were excluded. However, another two were identified from reference lists. Finally, a total of 25 relevant papers met the full inclusion criteria (Fig. 2.1).

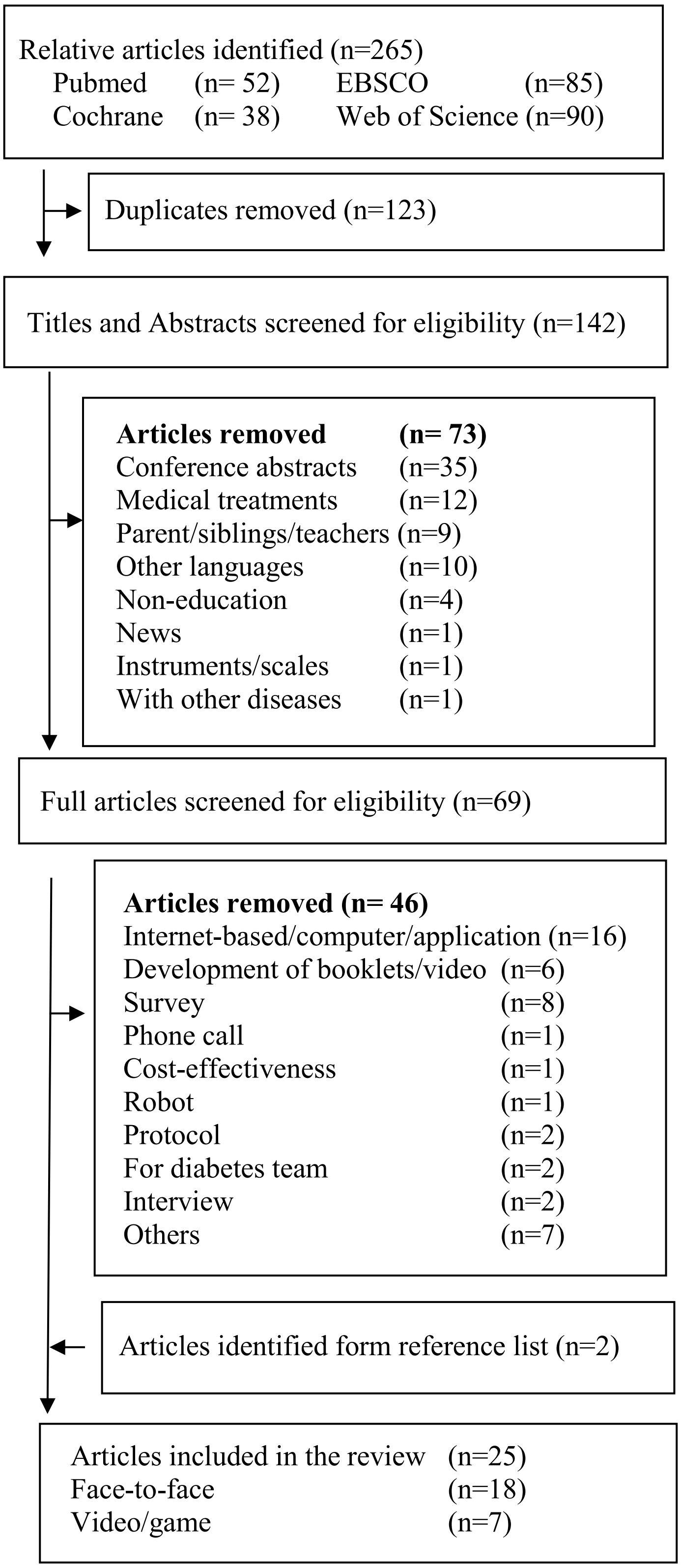


Fig 2.1. Flow chart of diabetes education of children and adolescents

(1) Diabetes education through face-to-face (or written materials)

In this review, 18 studies were found to conduct education through face-to-face means with children and adolescents with T1DM, which are presented under the following five sub-titles according to education contents, including nutrition (n=4), insulin education (n=3), blood sugar monitoring (n=1), comprehensive diabetes education (n=9), and reproductive health (n=1).

- Nutrition education in four articles

Four studies developed diabetes education programmes to improve dietary behaviours among children and adolescents with T1DM, including two RCTs in USA (Spiegel et al., 2012, Majumdar et al., 2015), a clustered RCT in UK (Price et al., 2016) and a prospective trial in Italy (Marigliano et al., 2013). Dietary education interventions were performed by Registered Nurses or Registered Dieticians in three studies (Spiegel et al., 2012, Majumdar et al., 2015, Price et al., 2016), and conducted by a pediatric diabetologist and a dietician in one study (Marigliano et al., 2013).

Carbohydrate counting was an important part of dietary education programmes in all the four studies, such as calculating carbohydrates from food labels, estimating portions accurately when eating out with no label available (Spiegel et al., 2012), introducing National Reference Dietary Intakes (RDIs) as reference values for nutrient intake (Marigliano et al., 2013), and recommending individualised age- and gender-specific daily carbohydrate intake (Majumdar et al., 2015). Written materials were also included in three studies to support education, such as quizzes (Price et al., 2016), nutrition labels (Spiegel et al., 2012) and a reproductive meal plan with several food options (Marigliano et al., 2013). Scenario-based teaching was also considered to provide education of diabetes complications (Price et al., 2016).

The results showed that carbohydrate counting in combination with diet education did not significantly reduce HbA1c in the four studies (Spiegel et al., 2012, Marigliano et al., 2013, Majumdar et al., 2015, Price et al., 2016), did not prevent excessive weight gain in one study (Majumdar et al., 2015), or even did not affect dietary habits, body composition and body fat distribution in one study (Marigliano et al., 2013) among children and adolescents with T1DM.

- Insulin education in three articles

Three studies were conducted to improve insulin injection skills, insulin adjustment (von Sengbusch et al., 2006, Clapin et al., 2017) or insulin pump usage (Deeb et al., 2017) among children with T1DM. An education session in the United Arab Emirates (Deeb et al., 2017) was specifically related to the alarm signaling system of the insulin pump. In this study, the warning and error signals were recorded and discussed with adolescents, as well as a summarised manual of signal description, to help them manage those signals. After targeted education, the adolescents' ability to deal with warning and error signals significantly improved (Deeb et al., 2017). Another education programme focusing on insulin functions and adjustment (von Sengbusch et al., 2006) was conducted with inpatients in eight hospitals in rural Germany. Although there was no difference in HbA1c after education, the rate of hospitalisation significantly decreased (von Sengbusch et al., 2006). A RCT (Clapin et al., 2017) compared the effects of home-based and inpatient-based insulin education programmes with identical education content and staff in Australia. There were no differences in medical or psychosocial outcomes among those groups. However, families preferred to choose home-based education, which also saved up to AUD 40,000 per month due to hospital bed day cost savings (Clapin et al., 2017).

- Blood glucose monitoring education in an article

A prospective study (Demir et al., 2019) was conducted in an outpatient clinic in Turkey to educate children and adolescents with T1DM to use a continuous glucose monitoring (CGM) system, as well as hypoglycemia management. The number of hypoglycemia events did not change after three-month education, and HbA1c levels also had a non-significant increase.

- Comprehensive diabetes education in nine articles

Comprehensive diabetes education in this review refers to at least two components of diabetes self-management involved in the education programmes, including insulin, diet, blood glucose monitoring and exercise. In total, nine studies presented the effectiveness of comprehensive diabetes education on children and adolescents with T1DM, including four RCTs (Howe et al., 2005, Wang et al., 2010, Murphy et al., 2012, Brorsson et al., 2019), two studies with repeated measures (Marshall et al., 2015, Mauri et al., 2017), two quasi-experimental studies (Abolfotouh et al., 2011, Hawkes et al., 2019) and a pre- and post-test study (Altundag and Bayat, 2016).

Among the nine studies, four were conducted in USA (Hawkes et al., 2019; Howe et al., 2005; Marshall et al., 2015; Wang et al., 2010), one in Australia (Murphy et al., 2012), one in Sweden (Brorsson et al., 2019), one in Italy (Mauri et al., 2017), one in Turkey (Altundag and Bayat, 2016) and another one in the Kingdom of Saudi Arabia (Abolfotouh et al., 2011). Specifically, diabetes education was conducted in pediatric diabetes clinics or centres (Howe et al., 2005, Murphy et al., 2012, Mauri et al., 2017), children's hospitals or medical centres (Wang et al., 2010, Brorsson et al., 2019, Hawkes et al., 2019), university or district hospitals (Marshall et al., 2015, Altundag and Bayat, 2016), or diabetes outpatient clinics (Abolfotouh et al., 2011). In addition, a study was also conducted in some social environments, such as theatre, cinema or a birthday party, to explore the effects of peer interactions on adolescents' adaptation to their diseases in daily life (Altundag and Bayat, 2016). In another study, an education programme ended with a four-day education summer camp in Italy, which provided intensive experimental education and also was an opportunity for adolescents to put all information learned into practice (Mauri et al., 2017).

Comprehensive education was performed by diabetes educators (Wang et al., 2010) or nurse practitioners (Howe et al., 2005), or conducted by a multidisciplinary team of health professionals, including dietician, child psychiatrist or social worker, in addition to nurses or certificated diabetes educators (Murphy et al., 2012, Altundag and Bayat, 2016, Mauri et al., 2017, Hawkes et al., 2019). Another three studies were conducted by group leaders (Brorsson et al., 2019), investigators (Abolfotouh et al., 2011) or trained care providers (Marshall et al., 2015) without further explanation.

Although education programmes consisted of comprehensive diabetes self-management, education contents varied between studies. Four studies (Wang et al., 2010, Murphy et al., 2012, Mauri et al., 2017, Hawkes et al., 2019) developed structured education programmes, which were designed to meet four key criteria, a structured and evaluated curriculum, trained educators, quality assured and being audited according to ISPAD guideline (Lange et al., 2014). Structured education curricula were presented in all of the four studies; however, a study reported that educators did not receive any training (Wang et al., 2010). In addition, a family-centred group education programme "Families and Adolescents Communication and Teamwork Study (FACTS)" was developed in an Australian study to motivate families to take their own responsibilities (Murphy et al., 2012). A person-centred communication and reflection education programme was conducted through different communication methods to encourage adolescents and parents to express their difficulties in diabetes management (Brorsson et al., 2019). A peer interaction and group education programme consisted of multiply training sessions, including warm-up game, narrating, discussion, role-play, and peer interaction in social environments, such as going to the theatre and cinema (Altundag and Bayat, 2016).

All nine studies evaluated the effectiveness of comprehensive diabetes education on HbA1c, seven of which reported significant changes in HbA1c except two studies (Howe et al., 2005, Murphy et al., 2012). Four studies (Wang et al., 2010, Abolfotouh et al., 2011, Murphy et al., 2012, Mauri et al., 2017) explored the effects of comprehensive education on quality of life, and only one (Abolfotouh et al., 2011) presented significant improvements. Three studies (Howe et al., 2005, Wang et al., 2010, Abolfotouh et al., 2011) included adherence as an outcome of comprehensive education, and two (Howe et al., 2005, Abolfotouh et al., 2011) reported significant improvement. In an RCT, both adolescents and parents in the intervention group were invited to attend a communication and reflection education programme, and adolescents in the control group received standard care and regular clinic visit. However, there was no difference in the degree of diabetes-related family conflicts between groups (Brorsson et al., 2019).

- Reproductive health education in an article

A pilot study (Kohn et al., 2018) in USA explored the effectiveness of a reproductive health education booklet "Diabetes and Reproductive Health for Girls" among girls with T1DM, which was published by the American Diabetes Association (ADA). The booklet was explained by an educator in a private room to girls and parents who were also invited to ask questions freely and privately. A promising trend was reported in improving adolescents' self-efficacy and knowledge of reproductive health.

(2) Videos/games/toys in seven articles

Videos, games, or toys make it easy for children and adolescents to understand educational materials and repeat lessons, especially for younger children (Emiliana et al., 2019). In this section, video, game and toy interventions refer to animated videos, games or toys which did not require internet access or a computer.

- Educational videos/games

Six studies explored the effects of videos or games on diabetes management among children and adolescents with T1DM, including three quasi-experiments in Indonesia (Emiliana et al., 2019; Tumakaka et al., 2019) and Taiwan (Wong et al., 2011), two RCTs in USA (Brown et al., 1997) and Brazil (Geremia et al., 2019), and a feasibility study in USA (Klingensmith et al., 2013). Adolescents received interventions through animated videos in four studies (Wong et al., 2011, Emiliana et al., 2019, Geremia et al., 2019, Tumakaka et al., 2019), via interactive video games in one study (Brown et al., 1997) and a game system in another study (Klingensmith et al., 2013).

Regarding the contents of these videos or games, three studies (Brown et al., 1997, Emiliana et al., 2019, Geremia et al., 2019) focused on comprehensive diabetes management. In an American study, adolescents aged 8-16 years were randomly assigned to the control group receiving an entertainment video game without diabetes-related content or to the intervention group receiving an interactive video game, in which players must help their character monitor blood sugar, inject appropriate amounts of insulin, review a diabetes logbook, and find food containing appropriate amount of calories. After 6 months, self-efficacy increased in the intervention group, however, there was no significant difference in diabetes knowledge and HbA1c between groups (Brown et al., 1997). A pilot RCT in Brazil explored the effects of a short-term experimental programme with five short animated videos and a programme in the control group through 45-minute PowerPoint lectures among young people with T1DM. HbA1c was found to be comparable between two groups (Geremia et al., 2019). A quasi-experimental study was conducted in Indonesia where an education tool in the form of animated videos named "PRISMA education" significantly improved self-management and compliance in children (6-18 years) with T1DM. However, only 31 participants were included in this study (Emiliana et al., 2019).

Another three programmes focused on a specific component of diabetes management in adolescents with T1DM, including exercise (Wong et al., 2011), blood glucose monitoring (Klingensmith et al., 2013) and sleep quality (Tumakaka et al., 2019). A quasi-experimental study designed a 12-week home-based aerobic exercise programme to encourage children and adolescents with T1DM to adhere to exercise. Upbeat music and different kinds of exercise, such as walking, running, and lifting, were combined and delivered by a Video Compact Disc (VCD). The result showed that the aerobic exercise programme had no significant effect on glycaemic control and peak oxygen uptake (Wong et al., 2011). In an acceptability study in USA, a blood glucose meter was connected with a handheld game system to transfer subjects' reward points from the meter to the video game, which was designed to motivate children and young adults (4-24 years) with T1DM to build good blood glucose monitoring habits. The game system was assessed by most participants to be good to excellent (Klingensmith et al., 2013). In an Indonesian quasi-experimental study, children (6-18 years) with T1DM received sleep hygiene education for 10 minutes via video, while those in the control group went to sleep in accordance with their daily habits. Participants' sleep hygiene significantly improved in the intervention group, compared with those in the control group (Tumakaka et al., 2019).

- Educational toys

A UK study (Kyfonidis and Lennon, 2019) designed tangible educational toys for younger children between 5-9 years with T1DM through a multiphase and user-centred design process. In total, 85 plastic food toys with the radio-frequency identification (RFID) tags were used, including 21 toys which were crafted by the researcher to look like foods in the supermarkets and other standard plastic food toys available in toy stores. The educational toys were evaluated by children, parents and clinicians from a paediatric diabetes clinic to be engaging (Kyfonidis and Lennon, 2019).

2.1.3 Conclusion

The effects of "traditional" education delivery methods on T1DM management in children and adolescents cannot be meta-analysed because of varied methods, contents and outcome measures. High quality RCTs were limited and there were few studies to compare the effects between different intervention methods among children and adolescents with T1DM. Therefore, it is hard to conclude which method is most effective. However, choosing appropriate diabetes education methods is important according to intervention contents and target participants.

In addition, new technologies also provide new means to manage diabetes, including internet, phone, app or telemedicine, which provide new ideas about the delivery of T1DM education and management among adolescents.

2.2. Effectiveness of internet and phone-based interventions on diabetes management of children and adolescents with T1DM: a systematic review

Aims: This review aimed to synthesise evidence about the impact of internet and phone-based diabetes education and management on metabolic control, self-management behavior changes, and psychological effects among children and adolescents with type 1 diabetes mellitus (T1DM).

Methods: Pubmed, EBSCO, Cochrane Library, Web of Science, Joanna Briggs Institute Library, and Chinese databases CNKI and Wanfang, were searched from 1989 to March 2020. Two reviewers independently selected randomized controlled trials (RCTs), in English and Chinese, which compared an intervention group of new technology-based diabetes education and management with a control group of usual care. The primary outcomes were metabolic control, such as glycated haemoglobin (HbA1c); secondary outcomes consisted of behavior changes and psychological effects, such as self-efficacy and quality of life.

Results: A total of 23 RCTs with 1824 participants met the inclusion criteria. The meta-analysis showed that phone calls could significantly reduce HbA1c (MD= -0.17, 95%CI: -0.33 to -0.01, I2= 0%) in children and adolescents with T1DM. New technology-based diabetes education and management could significantly improve self-efficacy (SMD= 0.37, 95%CI: 0.07 to 0.67, I2= 0%). No benefits on behavior changes and quality of life were identified.

Conclusion: New technology-based diabetes education has potential benefits for children and adolescents with T1DM, such as improving metabolic control through phone calls, and increasing their self-efficacy of diabetes management. Well-designed RCTs with larger sample sizes and longer intervention duration should be conducted, especially in the developing countries.

2.2.1. Introduction

According to the International Diabetes Federation (IDF), 1.11 million children and adolescents (<20 years) were estimated to have type 1 diabetes mellitus (T1DM) worldwide in 2019, which had increased by approximately 3% annually (IDF, 2019a). T1DM is a lifelong condition with autoimmune reaction and requires children and adolescents continuously to conform lifestyle and behaviors to their diabetes care regimen. However, physical growth, insulin resistance and psychological disorders during puberty pose a particular challenge to their diabetes self-management (Wherrett et al., 2013). Poor adherence to therapy is a common concern in children and adolescents with T1DM (Datye et al., 2015).

Across all age-groups, children and adolescents are currently the farthest from achieving a HbA1c goal of <7% (58 mmol/mol) (DiMeglio et al., 2018). In the USA, the mean HbA1c was 8.5% (69 mmol/mol) among those aged 6-12 years with T1DM and 9.0% among those aged 13-17 years, which was higher than the mean HbA1c of 8.4% for all age-groups (2.7-93.9 years) (Miller et al., 2015). This is consistent with results in Austria and Germany (Hofer et al., 2014). Elevated HbA1c values are associated with chronic complications, which are irreversible (Samuelsson et al., 2014). In addition, suboptimal glycaemic control has negative effects on physical growth, like near-adult height (Bonfig et al., 2012), cognitive development (Giannini et al., 2014) and regional brain structure in children and adolescents (Gaudieri et al., 2008).

Education is the key to successful diabetes management (Phelan et al., 2018). As more than 80% of young population (15-24 years) are online worldwide (Sanou, 2017), new technologies are recommended to be used in children and adolescents as one of the vehicles for education motivation (Phelan et al., 2018). Several systematic reviews examined the effects of a certain new technology on children and adolescents with T1DM. One integrative review explored the roles of telemedicine in school-age children and adolescents (8-20 years) with T1DM but without synthesized data (Guljas et al., 2014). A meta-analysis indicated no significant effects of telemedicine interventions on HbA1c, severe hypoglycemia and diabetic ketoacidosis in children and adolescents (<19 years) with T1DM (Shulman et al., 2010). Another integrative review showed that the effects of text message interventions on metabolic control and participants' satisfaction were mixed among children and adolescents (0-20 years) with T1DM (Herbert et al., 2013).

The present study updates a meta-analysis published in a Chinese journal to explore whether the internet and phone-based diabetes education and management were beneficial for children and adolescents with T1DM (Zhao et al., 2017), which was reproduced in Appendix 1. In this review, included searches were updated with reorganized results in a more comprehensive way, including the effects on blood glucose controlling, self-management behavior changes, and psychological effects.

2.2.2 Methods

This systematic review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline (see Appendix 2. PRISMA checklist).

(1) Search Strategy

Pubmed, EBSCO, Cochrane, Web of Science, Joanna Briggs Institute Library, and Chinese databases CNKI and Wanfang, were searched from 1989 to March 2020 because the World Wide Web was invented in 1989 and released to general public in 1991.

PICO elements (Methley, 2014) were used: *P(Population): "type 1 diabetes" and (child* or kid or adolescent or youth or young* or teen* or juvenile); I(Intervention): (internet or *phone or text or message or app* or web* or internet or "social media" or telemed* or Skype or facebook or "information technology"); C(comparison): "usual care" ; O(Outcome): ("glycaemic control" or "behaviour management" or "self-efficacy" or "quality of life");* Reference lists of publications were searched for potentially relevant articles.

(2) Inclusion and Exclusion Criteria

- Design

Any Randomised Controlled Trials (RCTs) in English and Chinese that explored the effectiveness of internet, phone-based interventions on diabetes management among children or adolescents with T1DM were included.

- Participants

Children or adolescents (<20 years) with T1DM were included (WHO, 2018a). Those who had serious reading or writing difficulties and were diagnosed with other diseases were excluded. Studies involving both children and parents were also included, which meant parents may or may not have been included among participants in the studies.

- Intervention

Intervention methods were based on internet or phone technologies, including phone call, text message, web, app, telemedicine, or Skype® and other social media.

- Outcomes

Outcomes included at least one of the following measures:

1) The primary outcome was glycaemic control, such as HbA1c;

2) The secondary outcomes included knowledge and behaviour changes, such as diabetes knowledge, exercise, insulin usage, blood glucose monitoring, diet, and self-reported adherence; and psychosocial outcomes, such as self-efficacy and quality of life. Outcome variables related to parents were omitted.

(3) Study selection

The process to select study was reviewed independently by the researcher and one of her colleague (Houquang Huang) who is familiar with systematic review, according to the inclusion and exclusion criteria mentioned above, including screening by titles, abstracts, and full articles.

(4) Quality Assessment

The risk of bias in eligible RCTs was assessed according to the Cochrane handbook (6.0 2019).

(5) Data Extraction

A standardised data extraction form was used to extract data from every study, which included the following details: author, participants, inclusion/exclusion criteria, sample size, intervention, follow up, measurement tools and main results.

(6) Selection of effect model and heterogeneity assessment in data synthesis

Effect size of individual studies was combined by using a random effect model because of different interventions methods and different scales involved to assess the same outcomes. The pooled effect size was presented by standardised mean difference (SMD) with 95% confidence intervals in most outcomes except HbA1c. Mean difference (MD) was used to calculate the pooled effect size of HbA1c.

I^2 statistic was used to assess the heterogeneity between studies. Values of $I^2 \leq 50\%$, 50-75%, and ≥75% were considered as low, moderate and high heterogeneity (Higgins et al., 2003). When the heterogeneity of pooled effect size was high, an individual study was removed at a time to assess if the heterogeneity could be reduced. The potential sources of heterogeneity were also explored by subgroup analysis or the assessment of design heterogeneity (Althuis et al., 2014).

2.2.3. Results

Of 780 abstracts originally screened, 117 were selected for further assessment after full articles reviewed. Finally, 23 studies met the inclusion criteria (Fig 2.2), including two studies identified from reference lists. All the studies were randomised controlled trials, including five pilots (Newton and Ashley, 2013, Berndt et al., 2014, Han et al., 2015, Stanger et al., 2018, Zhang et al., 2018), two randomised crossover trials (Rami et al., 2006, Klee et al., 2018) and two randomised waitlist controlled trials (Lehmkuhl et al., 2010, Hanberger et al., 2013). Only the data in the first period was extracted in the randomised crossover and waitlist trial designs.

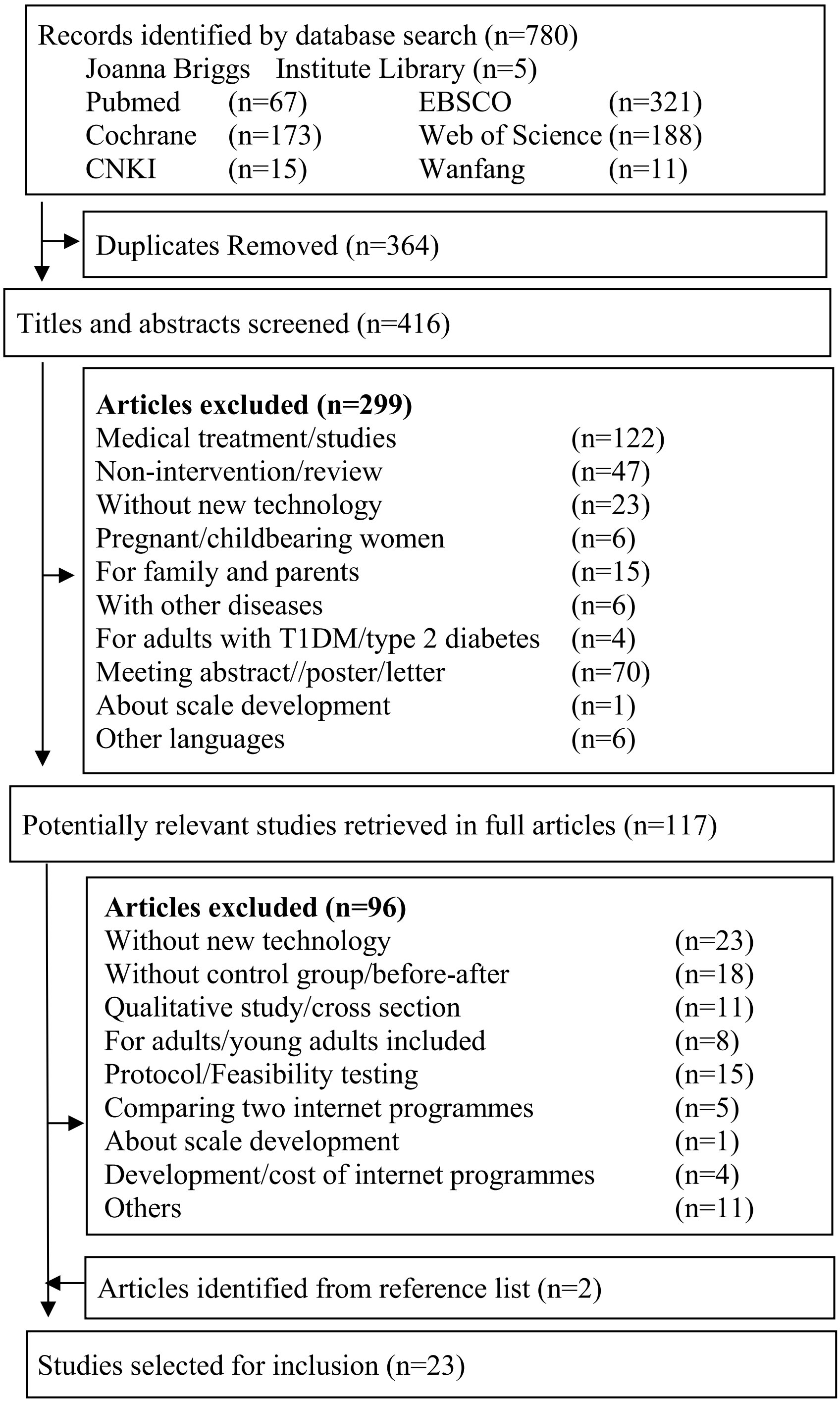


Fig 2.2. Flow chart of study selection in new tech-based diabetes management

(1) Participants and study characteristics

Participants in nine studies (Izquierdo et al., 2009, Lehmkuhl et al., 2010, Mulvaney et al., 2010, Newton and Ashley, 2013, Han et al., 2015, Stanger et al., 2018, Zhang et al., 2018, Freeman et al., 2013, Harris et al., 2015) were reported to be recruited from pediatric/diabetes clinics or centres, university affiliated hospitals, or academic medical centres (Zhang et al., 2018) in the USA, and other studies were conducted in Germany (Berndt et al., 2014), UK (Franklin et al., 2006), Sweden (Hanberger et al., 2013), Switzerland (Klee et al., 2018), Austria (Rami et al., 2006), Canada (Lawson et al., 2005, Goyal et al., 2017), New Zealand (Newton et al., 2009), Australia (Nunn et al., 2006), Greece (Chatzakis et al., 2019), Israel (Landau et al., 2012), Iran (Ebrahimpour et al., 2015, Rafeezadeh et al., 2019) and China (Ren et al., 2014). In one study (Izquierdo et al., 2009), adolescents with T1DM were recruited from 25 public schools in America. Most studies included adolescents with T1DM who were no more than 18 years old except four studies (Rami et al., 2006, Landau et al., 2012, Freeman et al., 2013, Harris et al., 2015), in which participants were 18-20 years. Parents were also involved in six studies (Nunn et al., 2006, Izquierdo et al., 2009, Lehmkuhl et al., 2010, Hanberger et al., 2013, Harris et al., 2015, Stanger et al., 2018) and caregivers were included in one study (Freeman et al., 2013). Ten studies (Lawson et al., 2005, Nunn et al., 2006, Rami et al., 2006, Lehmkuhl et al., 2010, Freeman et al., 2013, Han et al., 2015, Harris et al., 2015, Goyal et al., 2017, Stanger et al., 2018, Zhang et al., 2018) reported suboptimal glycaemic control as one of the inclusion criteria. Most studies reported the involvement of participants with diagnosis of T1DM more than 6 months or 1 year except five studies (Izquierdo et al., 2009, Newton et al., 2009, Freeman et al., 2013, Hanberger et al., 2013, Ebrahimpour et al., 2015). Sample size ranged from 20 to 494. Participants and study characteristics of the 23 studies were summarised in Appendix 3.

(2) Interventions

The intervention methods included text messages in four studies (Franklin et al., 2006, Newton et al., 2009, Han et al., 2015, Zhang et al., 2018), phone calls in two studies (Lawson et al., 2005, Nunn et al., 2006), mobile applications in four studies (Berndt et al., 2014, Goyal et al., 2017, Klee et al., 2018, Chatzakis et al., 2019), webpages in six studies (Mulvaney et al., 2010, Landau et al., 2012, Hanberger et al., 2013, Newton and Ashley, 2013, Ren et al., 2014, Stanger et al., 2018), telemedical support in three studies (Rami et al., 2006, Izquierdo et al., 2009, Lehmkuhl et al., 2010), social media in two studies (Freeman et al., 2013, Harris et al., 2015) and computer-based video games in two studies (Ebrahimpour et al., 2015, Rafeezadeh et al., 2019).

Intervention contents included: (1) multi-component self-management interventions, which reported at least two aspects of T1DM self-management, including blood sugar monitoring, nutrition, insulin injection and exercise; (2) a certain aspect of type 1 diabetes self-management; diabetes knowledge was reported in two studies (Han et al., 2015, Hanberger et al., 2013), blood sugar monitoring in two studies (Landau et al., 2012, Goyal et al., 2017), physical activity in one study (Newton et al., 2009); (3) other interventions, including Behavioural Family Systems Therapy (BFST) which was mentioned in three studies (Lehmkuhl et al., 2010, Freeman et al., 2013, Harris et al., 2015), discovering and resolving personal barrier to self-management in one study (Mulvaney et al., 2010), incentives to encourage adherence in two studies (Stanger et al., 2018, Rafeezadeh et al., 2019), and psychological intervention in three studies (Newton and Ashley, 2013, Ren et al., 2014, Ebrahimpour et al., 2015).

(3) Risk of bias assessment

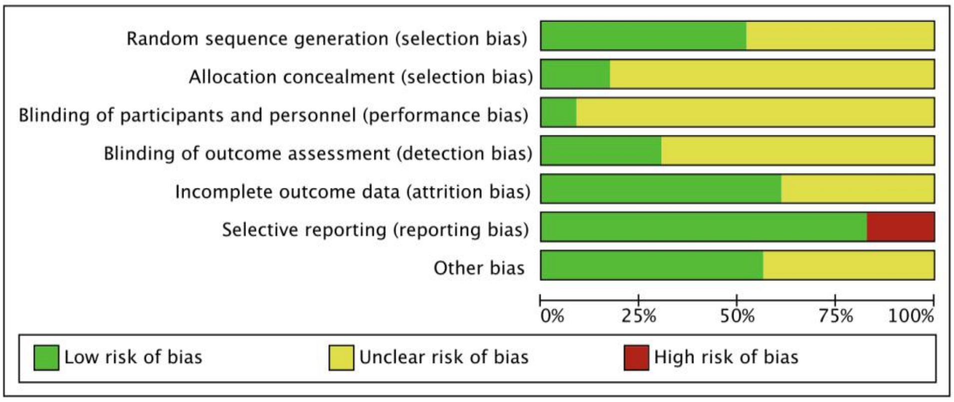


Fig 2.3. Risk of bias graph of new tech-based diabetes management

1) Random sequence generation

Although all studies were reported to be randomised controlled trials, only 12 studies were assessed as a low risk of bias in random sequence generation. Computer-generated random numbers and random numbers table were reported in five studies (Lawson et al., 2005, Franklin et al., 2006, Nunn et al., 2006, Landau et al., 2012, Klee et al., 2018) and two studies (Lehmkuhl et al., 2010, Hanberger et al., 2013), separately, which were assessed as low risk of bias. Stratified or block randomisation were reported in five studies, and three of them (Izquierdo et al., 2009, Mulvaney et al., 2010, Goyal et al., 2017) were assessed as low risk of bias and two studies (Harris et al., 2015, Chatzakis et al., 2019) were considered to be of unclear risk of bias because there were no further details mentioned. Random numbers were generated by using computerised minimum likelihood in one study (Stanger et al., 2018), which was assessed as a low risk of bias because minimisation can be considered to be equivalent to being random in the Cochrane handbook (5.1.0 2011). SPSS software was reported to generate random sequence in one study (Newton and Ashley, 2013), which was also assessed as a low risk of bias.

2) Allocation concealment

It was reported that participants were randomised to the intervention or control groups in all studies. However, three studies (Lawson et al., 2005, Mulvaney et al., 2010, Chatzakis et al., 2019) reported the use of opaque and sealed envelopes to allocate participants randomly. One study (Han et al., 2015) in which participants were given an envelope about allocation of groups was assessed as an unclear risk of bias because there were no details about the characteristics of the envelopes. SPSS software was used to allocate participants randomly in one study (Newton and Ashley, 2013), which was assessed to be a low risk of bias.

3) Blinding of participants and personnel

It was hard to achieve the blinding of participants and personnel owing to the nature of the interventions. However, it was mentioned that all personnel were blinded to group assignment for the first year in a randomised waitlist controlled trial (Hanberger et al., 2013). In another study (Lawson et al., 2005), although participants and diabetes nurse educators were aware of their treatment assignment, participants were guided to tell diabetes team members that they were in the Telephone Study but not to reveal their treatment assignment. The investigators, treating physicians, other diabetes team members, and data management personnel were blind to the participants' treatment assignment in this study, which was assessed as a low risk of bias.

4) Blinding of outcome assessment

Blinding of outcome assessment was reported in seven studies (Newton et al., 2009, Lehmkuhl et al., 2010, Hanberger et al., 2013, Berndt et al., 2014, Harris et al., 2015, Stanger et al., 2018, Chatzakis et al., 2019) which were assessed to be low risk of bias. Independent raters who were unfamiliar with participants were mentioned in two studies (Lehmkuhl et al., 2010, Harris et al., 2015). Although assessors were not blinded, questionnaires were completed online in private by participants in two studies (Berndt et al., 2014, Stanger et al., 2018). Mailed questionnaires and a stamped return envelope through an independent department were used to collect data in one study (Hanberger et al., 2013). Another study (Chatzakis et al., 2019) was assessed as a low risk of bias because of objective outcomes involved, such as HbA1c, and percentage of hypoglycaemic and hyperglycaemic events. Hypoglycaemic and hyperglycaemic events were diagnosed according to participants' blood glucose measurements.

5) Incomplete outcome data

Fourteen studies were assessed to be a low risk of bias, five of which (Lawson et al., 2005; Berndt et al., 2014; Ren et al., 2014; Ebrahimpour et al., 2015; Chatzakis et al., 2019) reported that all the participants took part until the end of the studies with further description. There were six studies (Newton et al., 2009; Lehmkuhl et al., 2010; Freeman et al., 2013; Han et al., 2015; Harris et al., 2015; Zhang et al., 2018) which reported the number of participants lost to follow-up without attrition reasons, and three studies (Rami et al., 2006; Izquierdo et al., 2009; Mulvaney et al., 2010) did not reported any information about attrition, which were assessed to be unclear risk of bias.

6) Selective reporting

Four studies (Newton et al., 2009, Freeman et al., 2013, Hanberger et al., 2013, Berndt et al., 2014) did not present all the outcome measures mentioned before, which was assessed to be a high risk of bias. The remaining studies reported all the measures no matter whether they were statistically significant or not, which were assessed to be a low risk of bias.

7) Other potential sources of bias

Ten studies were assessed to have an unclear risk of bias, including a small sample size (<40) in four studies (Han et al., 2015; Ebrahimpour et al., 2015; Lehmkuhl et al., 2010; Rami et al., 2006) or short intervention period (2-8 weeks) in another four studies (Berndt et al., 2014; Ebrahimpour et al., 2015; Newton et al., 2013; Zhang et al., 2018), self-reported measures, such as self-reported physical activity and hypoglycemia event, which may be inaccurate in two studies (Newton et al., 2009, Klee et al., 2018), and without information about reliability and validity testing of the scales in one study (Ren et al., 2014). The rest were reported to be low risk of bias because they appeared to be free of other bias.

2.2.4. Outcomes

(1) Metabolic control

1) The effect of internet and phone-based interventions on HbA1c

All of the studies except three (Freeman et al., 2013, Newton and Ashley, 2013, Ebrahimpour et al., 2015) included HbA1c as an outcome to assess the effectiveness of interventions based on new information technologies, including internet and phone, on metabolic control. Another four studies (Izquierdo et al., 2009, Lehmkuhl et al., 2010, Klee et al., 2018, Zhang et al., 2018) could not be synthesised owing to the missing original data of HbA1c, which reported failure to demonstrate a significant impact of internet and phone-based interventions on HbA1c.

Sixteen studies reported the original data of HbA1c from 1530 adolescents with T1DM. The pooled analysis did not show a significant reduction (MD= -0.13, 95%CI: -0.33 to 0.06) in the random effect model and there was a high heterogeneity (I^2=78%) between studies. The heterogeneity reduced into moderate (I^2= 51%) after removing one study (Stanger et al., 2018); however, the exclusion of the study did not change the result (MD= -0.10, 95%CI: -0.27 to 0.07) (Fig 2.4). In addition, subgroup analysis was also conducted. The effectiveness of different intervention methods on HbA1c remained non-significant in three subgroups, including text group (MD= -0.07, 95%CI: -0.45 to 0.31, three studies pooled), mobile application group (MD= -0.21, 95%CI: -0.68 to 0.27, three studies pooled) and webpages group (MD= 0.02, 95%CI: -0.42 to 0.46, five studies pooled), except the phone calls group (MD= -0.17, 95%CI: -0.33 to -0.01, two studies pooled). The heterogeneity of the four subgroups was low to moderate (I^2= 0% -

66%) except in the webpages group (I^2= 90%). While the heterogeneity in the webpages group reduced into low (I^2= 2%) after exclusion of one study (Stanger et al., 2018), there was still no statistically significant conclusion (MD= 0.08, 95%CI: -0.11 to 0.28) (Fig 2.5).

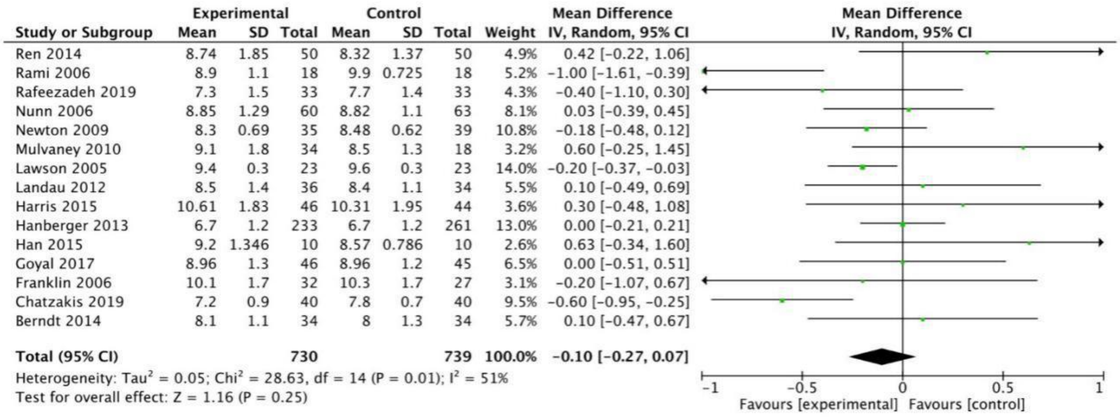


Fig 2.4. The effects of new tech-based interventions on HbA1c

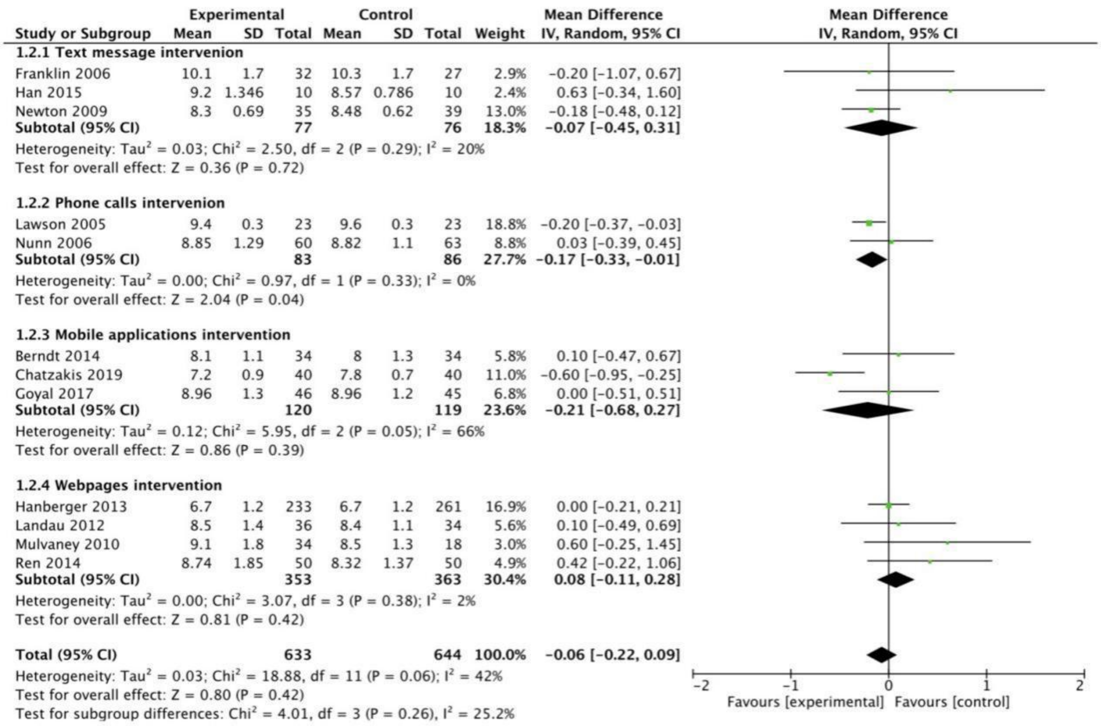


Fig 2.5. Subgroup analysis of effects of new tech-based interventions on HbA1c

2) The effect of internet and phone-based interventions on Body Mass Index (BMI)

Four studies (Lawson et al., 2005, Franklin et al., 2006, Newton et al., 2009, Berndt et al., 2014) explored the effects of internet or phone-based diabetes management on BMI. Standardised Mean Difference (SMD) with 95% confidence intervals was selected to summarise the outcomes because of different units between BMI in two studies (Lawson et al., 2005, Berndt et al., 2014) and BMI Z-scores in two studies (Franklin et al., 2006, Newton et al., 2009). BMI Z-scores, or BMI standard deviation (s.d.) scores are based on growth charts to measure the relative weight adjusted for children's age and sex (Must and Anderson, 2006). The interventions produced non-significant reduction in BMI (SMD= -0.19, 95%CI: -0.44 to 0.06) with a low heterogeneity (I^2= 0%) (Fig 2.6).

	Experimental			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Berndt 2014	20.1	3.5	34	22.2	5.7	34	27.2%	−0.44 [−0.92, 0.04]
Franklin 2006	0.42	0.87	32	0.34	0.81	27	24.0%	0.09 [−0.42, 0.61]
Lawson 2005	22.3	3.4	23	23.7	4.8	23	18.6%	−0.33 [−0.91, 0.25]
Newton 2009	0.626	0.27	35	0.656	0.28	39	30.2%	−0.11 [−0.56, 0.35]
Total (95% CI)			**124**			**123**	**100.0%**	**−0.19 [−0.44, 0.06]**

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.55$, df = 3 (P = 0.47); $I^2 = 0\%$
Test for overall effect: Z = 1.49 (P = 0.14)

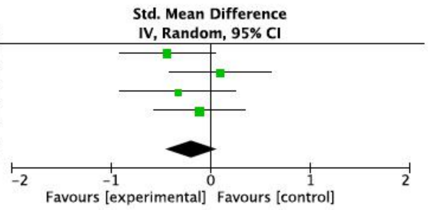


Fig 2.6. The effect of new tech-based interventions on BMI

3) The effect of internet and phone-based interventions on adverse outcomes

Five trials (Lawson et al., 2005, Franklin et al., 2006, Rami et al., 2006, Izquierdo et al., 2009, Landau et al., 2012) reported the episodes of diabetes ketoacidosis (DKA) as an outcome. There were the same or fewer episodes of DKA in the intervention groups except in one study (Landau et al., 2012), which only reported one episode of DKA in the intervention group. However, there were no significant changes reported between groups.

Eight studies (Franklin et al., 2006, Rami et al., 2006, Izquierdo et al., 2009, Landau et al., 2012, Hanberger et al., 2013, Goyal et al., 2017, Klee et al., 2018, Chatzakis et al., 2019) included hypoglycemia as an outcome. Five of them only reported severe hypoglycemia, and one study (Goyal et al., 2017) described the episodes of moderate and severe hypoglycemia separately, and another study (Klee et al., 2018) reported the episodes of mild, moderate and severe hypoglycemia together. Blood glucose below 70mg/dl (3.9 mmol/L) was categorised as hypoglycemia in one study (Chatzakis et al., 2019), in which there was no evidence for a beneficial benefit of internet or phone-based interventions on the episodes of hypoglycemia.

Hyperglycaemic events were presented as an outcome in two studies (Izquierdo et al., 2009, Chatzakis et al., 2019), which was defined as above 180mg/dl (10 mmol/L) at two-hour postprandial measurement in one study (Chatzakis et al., 2019). The result showed hyperglycaemia events significantly reduced at 12 months in the intervention group, compared with the control group in one study (Chatzakis et al., 2019). In another study, one severe hyperglycaemia event was found in the control group, but none in the intervention group (Izquierdo et al., 2009).

(2) Knowledge and behaviour changes in diabetes self-management

1) The effect of internet and phone-based interventions on diabetes knowledge

Two studies (Franklin et al., 2006, Nunn et al., 2006) assessed the effectiveness of internet and phone-based interventions in improving diabetes knowledge among children and adolescents with T1DM. The data were synthesised in a random effect model and presented by Standardised Mean Difference because two different scales were used, including Diabetes Knowledge Assessment (DKN) scales in one study (Franklin et al., 2006) and a modified version of the Test of Diabetes Knowledge (mTDK) in another study (Nunn et al., 2006). The pooled effect size did not show a statistically significant improvement in diabetes knowledge (SMD= -0.05, 95%CI: -0.34 to 0.24) with a low heterogeneity (I^2= 0%) (Fig 2.7).

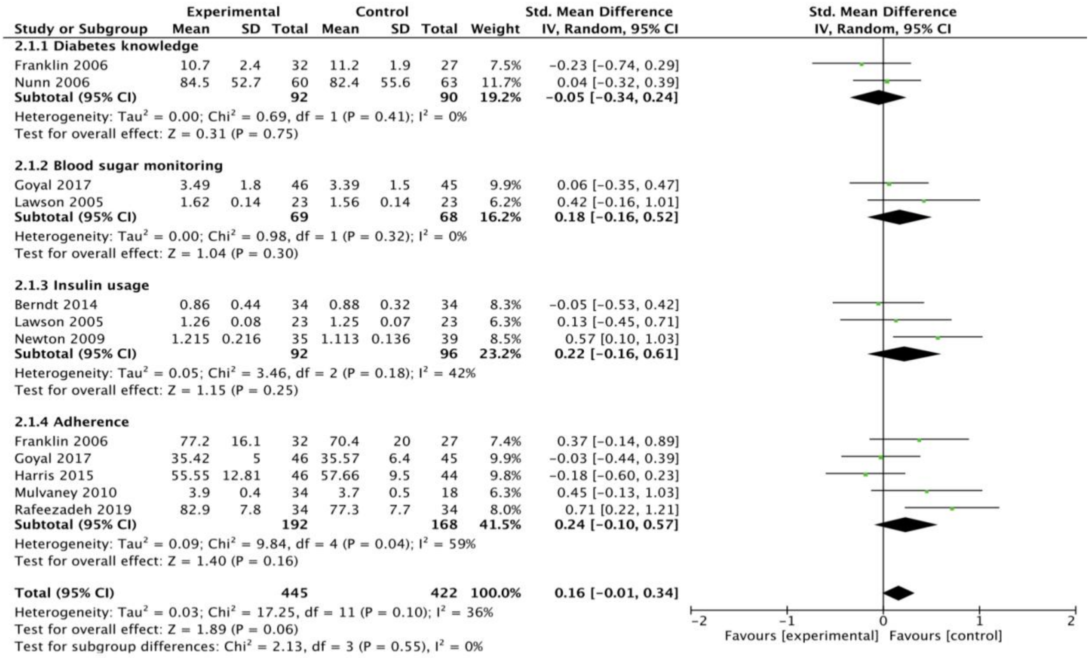


Fig 2.7. The effect of new tech-based interventions on behaviour changes

2) The effect of internet and phone-based interventions on blood glucose monitoring

Three studies (Lawson et al., 2005, Goyal et al., 2017, Stanger et al., 2018) reported the effect of interventions on blood sugar monitoring, which was measured by the mean number of daily self-monitoring of blood glucose. With the random effects model, the pooled analysis did not show any significant changes between the groups (SMD= 1.31, 95%CI: -0.48 to 3.11) with a high heterogeneity (I^2= 96%). The heterogeneity reduced (I^2= 0%) after exclusion of one study (Stanger et al., 2018), and the conclusion (SMD= 0.18, 95%CI: -0.16 to 0.52) had no change (Fig 2.7).

3) The effect of internet and phone-based interventions on insulin usage

Three studies (Lawson et al., 2005, Newton et al., 2009, Berndt et al., 2014) explored the internet and phone-based interventions on insulin use, which was measured by insulin dose per kilogram body weight (I.U./kg) in one study (Berndt et al., 2014) and total daily insulin dose per kilogram body weight (units/kg/d) in two studies (Lawson et al., 2005, Newton et al., 2009). There was no evidence that internet and phone-based interventions could help children and adolescents with T1DM reduce the usage of insulin (SMD= 0.22, 95%CI: -0.16 to 0.61, I^2= 42%) (Fig 2.7).

4) The effect of internet and phone-based interventions on exercise

Two studies (Nunn et al., 2006, Newton et al., 2009) measured the effects of interventions on exercise. The data from the two studies was not synthesised because frequency of activities per week were measured in one study (Nunn et al., 2006) and the minutes of moderate and vigorous physical activities per week (min/week) in another study (Newton et al., 2009). There was no significant improvement of exercise reported in the two studies.

5) The effect of internet and phone-based interventions on adherence

Five studies (Franklin et al., 2006, Mulvaney et al., 2010, Harris et al., 2015, Goyal et al., 2017, Rafeezadeh et al., 2019) reported the effectiveness of internet and phone-based interventions on adherence of self-management among children and adolescent with T1DM. Their adherence was measured by using a single item visual analogue scale (Franklin et al., 2006), the Self Care Inventory (SCI) (Goyal et al., 2017), the Diabetes Self-Management Profile-Diabetes (DSMP) (Harris et al., 2015), and the Diabetes Behaviour Rating Scale (Mulvaney et al., 2010); and the Diet-Exercise Regimen Adherence Questionnaire which was designed by the researcher with acceptable reliability and validity testing results (Rafeezadeh et al., 2019). With the random effects model, there was non-significant improvement in adherence (SMD= 0.24, 95%CI: -0.10 to 0.57) after intervention with a medium heterogeneity (I^2= 59%) (Fig 2.7).

(3) Psychosocial outcomes

1) The effect of internet and phone-based interventions on self-efficacy

Three studies (Franklin et al., 2006, Newton and Ashley, 2013, Berndt et al., 2014) assessed the effects of interventions on self-efficacy, which was measured by using Diabetes Self-Efficacy Scale (Berndt et al., 2014), Self-Efficacy for Diabetes scale (SED) (Franklin et al., 2006), and Self-Efficacy of Diabetes Self-Management (Newton and Ashley, 2013). The pooled effect size showed a statistically significant improvement in self-efficacy (SMD= 0.37, 95%CI: 0.07 to 0.67) with a low heterogeneity (I^2= 0%) (Fig 2.8).

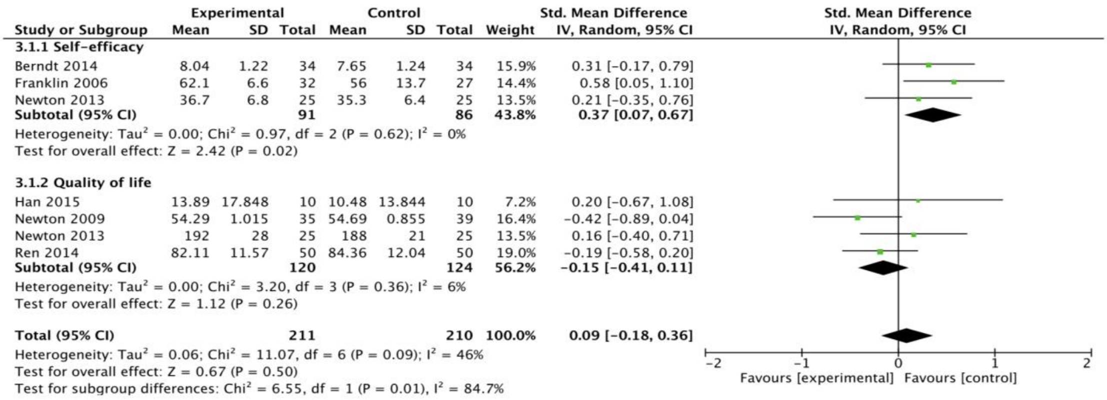


Fig 2.8. The effect of new tech-based interventions on psychosocial outcomes

2) The effect of internet and phone-based interventions on quality of life

Eight trials (Lawson et al., 2005, Izquierdo et al., 2009, Newton and Ashley, 2013, Newton et al., 2009, Berndt et al., 2014, Ren et al., 2014, Han et al., 2015, Goyal et al., 2017) explored the effects of interventions on quality of life. Five (Lawson et al., 2005, Izquierdo et al., 2009, Berndt et al., 2014, Han et al., 2015, Goyal et al., 2017) selected the Diabetes Quality of Life for Youth questionnaire (DQOLY) and the Pediatric Diabetes Quality of Life (PedsQL)-Diabetes Module to measure the quality of life among children and adolescent, which could not be synthesised in a meta-analysis because only sub-scale scores were reported. The studies, except one (Han et al., 2015) reported that the use of new technology significantly improved some aspects of quality of life, there was no significant improvement reported in the other four studies. The data from another four studies (Newton et al., 2009, Newton and Ashley, 2013, Ren et al., 2014, Han et al., 2015) with 244 participants was summarised in the meta-analysis, which also showed no statistically significant improvement in quality of life after interventions based on new technology (SMD= -0.15, 95%CI: -0.41 to 0.11, I^2= 6%) (Fig 8). One study (Han et al., 2015) assessed the effects of interventions on quality of life among children and adolescents by using two scales at the same time, the DQOLY and the updated version of the Problem Areas in Diabetes (PAID). The data of the PAID scale was synthesised as shown in Figure 2.8.

2.2.5. Discussion

The results in this meta-analysis showed that phone call interventions could help children and adolescents with T1DM improve blood glycaemic control, and internet and phone-based interventions could improve self-efficacy among children and adolescents with T1DM.

There was no statistically significant effect of internet-based interventions on glycaemic control in this meta-analysis. Although phone call interventions were presented to help children and adolescents with T1DM improve HbA1c, only two studies were included. Another three integrative reviews also explored the effects of information technology-based interventions on HbA1c among children with T1DM; however, the results varied and interventions methods were different between reviews, including text (Herbert et al., 2013), Telemedicine (Guljas et al., 2014) and smartphone (Sun et al., 2019), separately. Another meta-analysis (Shulman et al., 2010) reported a non-significant pooled effect size of Telemedicine interventions on HbA1c, which included both RCT and CCT.

Therefore, high-quality RCTs comparing the effects of a certain new technology-based intervention method, such as text, phone calls, telemedicine, or apps, with usual care on blood glucose still need to be explored further. In addition, effectiveness of internet and phone-based interventions on HbA1c is non-significant in three subgroups, which is different from what was expected in this meta-analysis. The reasons may include: 1) Different HbA1c inclusion criteria were included in different studies. Ten studies mentioned suboptimal glycaemic control as one of the inclusion criteria, which also varied from HbA1c ≥ 7.5% to HbA1c ≥ 9%; 2) The durations of the studies were no more than 6 months in 14 studies. Long-term effectiveness of information technology-based interventions on HbA1c needs to be explored. In addition, limited studies were included in the subgroup analysis of HbA1c. Therefore, although the data from 1469 children and adolescents with T1DM was summarised in this meta-analysis, the results about HbA1c should to be generalised with caution. There were also no beneficial benefits of internet or phone-based interventions on the episodes of DKA, hypoglycemia and hyperglycaemia in this meta-analysis, which was similar to the pooled effect sizes in another meta-analysis (Shulman et al., 2010). However, the episodes of hypoglycemia could be downgraded because it was mentioned that the episodes of hypoglycemia were self-reported or reviewed from patient's diary.

The effects of internet and phone-based interventions on knowledge and behaviour changes were not significant in four subgroups with objective measures, including learning diabetes knowledge, blood glucose monitoring, insulin use, and exercise. This was consistent with the result of adherence which was assessed by adolescents themselves as a subjective measure. There were no high-quality RCTs which explored the effects of information technology-based interventions on diet management among children and adolescents with T1DM. However, the results of this review also need to be generalised with caution because of small sample sizes and the few studies which explored the effects on diabetes knowledge and behaviour improvement. In addition, according to the psychosocial theories, health behaviour is influenced by many factors in social cognition models and behaviour change involves movement through a sequence of discrete and qualitatively distinct stages in stage models (Sutton, 2001). Therefore, it is a long and complicated process to change diabetes management behaviours. The findings from another systematic review showed that internet-based health behaviour interventions that incorporated more behaviour change techniques tended to have larger effects (Webb et al., 2010). However, only two studies included Bandura's self-efficacy theory in the interventions.

This meta-analysis indicated a statistically significant improvement in self-efficacy among children and adolescents with T1DM. A significant improvement was also reported in one study (Franklin et al., 2006) of another systematic review (Wangberg, 2008), which was also involved in this meta-analysis. It was supported that self-efficacy was a moderator of internet-based diabetes education and diabetes self-care behaviours (Wangberg, 2008). Therefore, the interventions in future trials could also focus on enhancing self-efficacy, which may be beneficial to improve diabetes self-management behaviours. Regarding quality of life, non-significant effect of information technology-based interventions on quality of life was observed in this meta-analysis. Another systematic review with involvement of three studies reported the effects of telemedicine interventions on diabetes-related quality of life, and non-significant differences were found between the intervention and control groups (Shulman et al., 2010). In this meta-analysis, different scales were used to assess diabetes-related quality of life in adolescents, which caused the difficulties to synthesise the data of all the studies.

The results of this meta-analysis need to be generalised with caution because of the limitations of the original studies:

First, sample sizes were small. Nineteen out of 23 studies included no more than 80 participants in each study, which would result from smaller percentage of adolescents with T1DM worldwide, compared with adults with type 2 diabetes. In addition, internet access would also be a limiting factor, which may lead to the difficulty of participation in studies for those adolescents from lower-income families.

Second, the short durations in the interventions should be paid attention to as mentioned before. Blood glucose controlling and behaviour change of diabetes self-management could be a long and complicated process, which may be one of the reasons why no significant effect was found on glycaemic control and behaviour changes in this meta-analysis.

Third, different scales were used to test the same outcomes. Although the heterogeneity was low to moderate in this meta-analysis, the data from some studies could not be synthesised owing to different scales or units being used, such as quality of life. In addition, some outcomes could be measured by using objective assessments, rather than self-reported scales, such as episodes of hypoglycemia.

Fourth, few studies were included in the subgroup analysis about the effects on HbA1c. The randomised controlled trials with a high quality still need to be explored. However, it was hard to achieve blinding of participants and personnel in technology-based interventions; only 12 studies mentioned the details of generating random sequences, and four studies included the methods of allocation concealment and seven studies achieved blinding of outcome assessment.

In addition, 20 studies were conducted in developed countries, or in Europe and America. Only one study was completed in China (Ren et al., 2014). Therefore, the effects of information technology-based diabetes interventions could be explored further in the developing countries, especially outside of Europe and America.

2.2.6. Conclusion

Regular phone calls could help children and adolescents with T1DM control their blood glucose, and internet and phone-based diabetes interventions could improve their self-efficacy of diabetes self-management. However, because of the limitations mentioned, the results need to be generalised with caution. In the future, the well-designed RCTs with larger sample sizes and longer intervention duration should be conducted worldwide by using a certain technology-based intervention method, especially in the developing countries.

2.3. Purpose of the current study

1) To develop a web-based diabetes educational material for children and adolescents (10-19 years) with T1DM in China based on the health belief model;

2) To develop webpages and upload the material online for children and adolescents to study;

3) To test the reliability, validity and utility of the webpages;

4) To test the feasibility of the web-based diabetes educational material;

CHAPTER 3 CONCEPTUAL FRAMEWORK

3.1. Theory selection process for health education and health behaviour

A theory is a set of general principles to explain events, behaviours or situations, which plays an important role in development, implementation and assessment of health research and practice. Programmes to improve health behaviour, including education interventions, are more likely to benefit participants if the interventions are based on a theory of health behaviour. The theories can help researchers identify the targets for change and the methods to complete the changes in health education and health behaviour (Crosby et al., 2013).

Results of health education not only depend on individual effort to change health behaviour, but also on environmental activities, organisational efforts, community-level programmes and economic support. The theories of health education and health behaviour focus on multiple determinant factors of behaviour at the individual, interpersonal, group, organisational, and community levels (Glanz et al., 2008). However, this thesis only focused on individual efforts to promote adherence to diabetes self-management among adolescents. Therefore, although social cognitive theory (SCT) has been commonly used to improve health education and health promotion, SCT views human behaviour as the products of combination of personal, behavioural and environmental influences, which is not suitable for this research (Glanz et al., 2008).

In addition, according to a review of health education and health behaviour theories, the theories to predict, explain and change individual health behaviour consist of two main groups, which are stage models and social cognition models (Munro et al., 2007; DeBarr et al., 2004). Social cognition models refer to a group of theories which take several cognitive and affective factors, such as beliefs and attitudes, as the determinants of health behaviour. Stage models assume that people in different stages require different interventions to help them move to the next (Sutton, 2001). The comparison between these behaviour theories is summarised in Table 3.1.

Table 3.1. Behaviour theories and core constructs

Theories		Core construct
Social Cognition Models (Sutton, 2001; Glanz, 2008)	The Health Belief Model (HBM)	• Developed in 1950s; • There are four core constructs: perceived susceptibility, severity, benefits and barriers, which are commonly combined to influence the likelihood of performing the behaviour.
	Protection Motivation Theory (PMT)	• Developed in 1983; • It can be regarded as an adaption of the HBM; • Protection motivation is usually defined as the intention to adopt the recommended action; • The four most empirical intentions are vulnerability and severity, response efficacy, and perceived self-efficacy.
	Self-efficacy theory (SET)	• A subset of Bandura's social cognitive theory in 1986; • The two key determinants of behaviour are perceived self-efficacy and outcome expectancies;
	The Theory of Reasoned Action and the Theory of Planned Behaviour (TRA/TPB)	• TRA believes people will have strong intentions to perform a given action if they evaluate it positively and if they believe that important others think they should perform it; • In TPB, a variable called perceived behavioural control was added to the TRA because many behaviours cannot simply be performed at will; they require skills and opportunities;
Stage models (Sutton, 2001; Glanz, 2008)	The transtheoretical model; the precaution adoption process model; the health action process approach; the health behaviour goal model;	• They are fundamentally different in structure from social cognition models; • According to this approach, behaviour change involves movement through a sequence of discrete, qualitatively distinct, stages; • The transtheoretical model (TTM) specifies five stages: precontemplation, contemplation, preparation, action, and maintenance;

3.2. Why was Health Belief Model selected and its theoretical framework

As mentioned above, stage models are not appropriate because this research did not focus on making specific measures to change individuals' behaviours step by step. On the contrary, the research aimed to explore why people did or did not adhere to certain kinds of health care regimens, in order to improve the adherence of health behaviour. Among social cognition models, Health Belief Model (HBM) provides a more comprehensive explanation of what factors may influence individuals to change and maintenance of health-related behaviours, which was selected to provide framework for the study (Sutton, 2001).

The HBM contains six primary concepts that predict why individuals would take action to prevent, or to control a certain disease, including susceptibility, seriousness, benefits and barriers to a behaviour, cues to action, and self-efficacy. In theory, if individuals perceive themselves as susceptible to a certain illness condition, believe that condition would have potentially serious consequences, believe that a set of actions available to them would be beneficial to reduce their susceptibility or severity of the condition, and believe the benefits of taking action outweigh the costs of action, they are more likely to take action to do what they believe to reduce the risks. Except as one of the most widely used conceptual frameworks in health behaviour research, HBM was selected in this study as owing to the reasons as follows:

First, the HBM has an intuitive logical and clearly stated central tenets. As shown below, arrows indicate pathways through which constructs are linked to each other and to health behaviour (Fig 3.1). The model is a proven way to identify correlates of health behaviour and is useful for informing intervention design and evaluation.

Second, the model contains six primary constructs that predict whether and why people will act to prevent, detect, or control illness conditions. Every construct has its concept definition and intervention strategies to influence concept, which specifically provide guidance about how to make interventions. Therefore, it is relatively easy to use and apply.

Third, HBM has been used successfully to predict and explain cancer screening and HPV vaccination (Zare et al., 2016). Some researchers have applied HBM to DM (Ahmad et al., 2014), and many of them approved efficiency of the HBM in prediction of self-care behaviour among patients with diabetes.

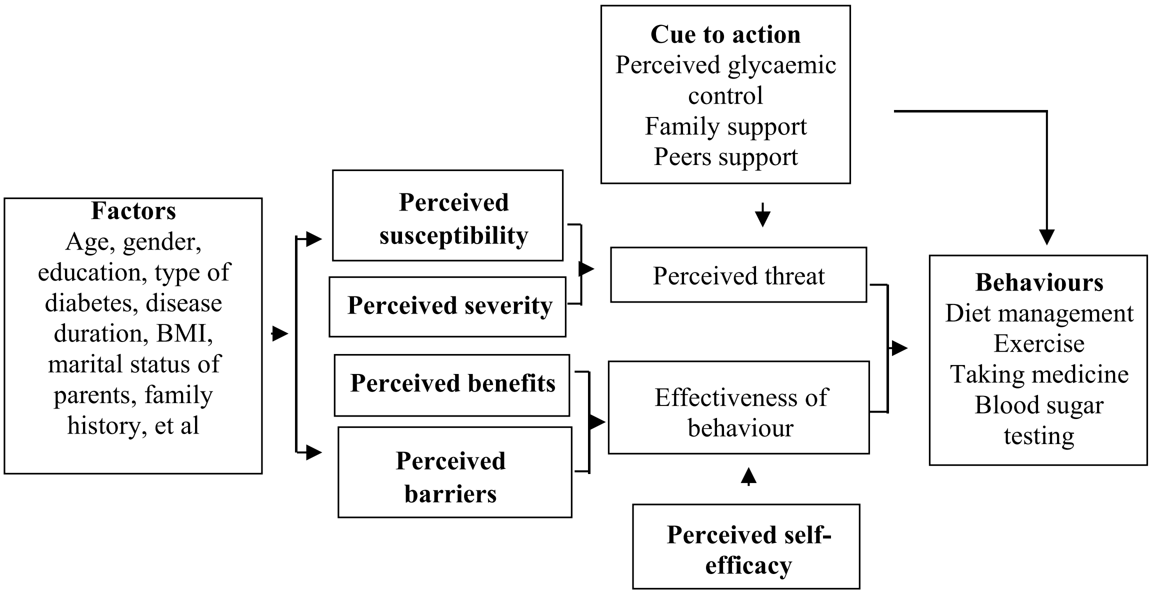


Fig 3.1. The theoretical framework of the Health Belief Model

3.3. How would the Health Belief Model be used in this research

According to a systematic review, four types or degrees of theory use were developed along a continuum, including informed by theory, applied theory, testing theory, and building theory, which was based on the authors' analyses and summary of how theory has been used in published articles (Painter et al., 2008).

- Informed by theory (69.1% of articles): a theoretical framework was identified, but no or limited/partial application of the theory in study components and measures. For example, one study chose the Health Belief Model (HBM) to guide the development of intervention materials, but no applications of HBM constructs were explicitly described, and no HBM constructs were measured.

- Applied theory (17.9% of articles): a theoretical framework was specified, and several constructs were applied in certain parts of the study. For example, a study aimed to develop intervention materials based on the HBM and addressed cues to action and perceived threat.

- Testing theory (3.6% of articles): a theoretical framework was specified, and more than half of the theoretical constructs were measured or explicitly tested, or two or more theories were explicitly compared to each other in the study. For example, a study stated that the HBM was used to develop intervention materials, which used and measured five key constructs (except self-efficacy) in the intervention and evaluation. Mediation analyses were conducted with indicators of these constructs.

- Building or creating theory (9.4% of articles): developing new or expanded theories by using constructs specified, measured, and analysed in a study (Painter et al., 2008).

In this thesis, the Health Belief Model was used to inform this study. Specifically, the Health Belief Model was used to develop a type 1 diabetes educational material for adolescents with T1DM, and no HBM constructs were measured because this study was a feasibility testing study with a small sample size. In future, testing of the HBM theory would be proposed in the final study with a big sample size.

3.4. The purpose of the study and outcome selection

The study aims to develop a reliable and valid web-based educational material to help adolescents with T1DM improve diabetes knowledge, self-efficacy and adherence of diabetes management. The three outcomes were selected mainly according to the HBM theory and the results of outcomes measures in systematic review in chapter 2.

First, three aspects of outcomes were reported in systematic review in chapter 2, including glycaemic control, diabetes knowledge and behaviour change, and psychological outcomes. This study was a feasibility testing study with a short research duration, which would be not long enough to change participants' blood glucose and behaviours related to diabetes self-management, however, improving diabetes knowledge, adherence and self-efficacy would be possible.

Second, as shown in Figure 3.1, the HBM was often used to explain the maintenance of health-related behaviours, which is consistent with adherence to diabetes management in this study.

Moreover, self-efficacy was a definition developed by Bandura to describe individuals' confidence to adherence to health behaviour, which was added to the HBM as a separate construct in 1988 (Glanz et al., 2008). For behaviour change or adherence to succeed, individuals also must feel that they are capable of taking action. As shown in Figure 3.1, self-efficacy plays an essential role in mediation between other five constructs and behaviour change of maintenance. In addition, it was tested whether diabetes education had an beneficial effect on self-efficacy among adolescents with T1DM in chapter 2. Therefore, self-efficacy was also included in outcomes of this study to be tested further.

CHAPTER 4 OUTLINE OF METHODOLOGY

This study aimed to develop web-based educational material for adolescents diagnosed with T1DM in China to improve their diabetes knowledge, self-efficacy and adherence, which was guided by following research questions: 1) Is it feasible to develop web-based educational material for adolescents with T1DM?; 2) Is it feasible to test the reliability, validity and utility of the webpages developed in this study?; 3) Are the recruitment and retention strategies feasible in the feasibility testing study?

As shown in Figure 4.1, the methodology consisted of developing the educational material, selection of scales, webpage development, and reliability, validity and utility of the webpages, as well as a feasibility study to test if the recruitment strategy and data collection process were possible or achievable.

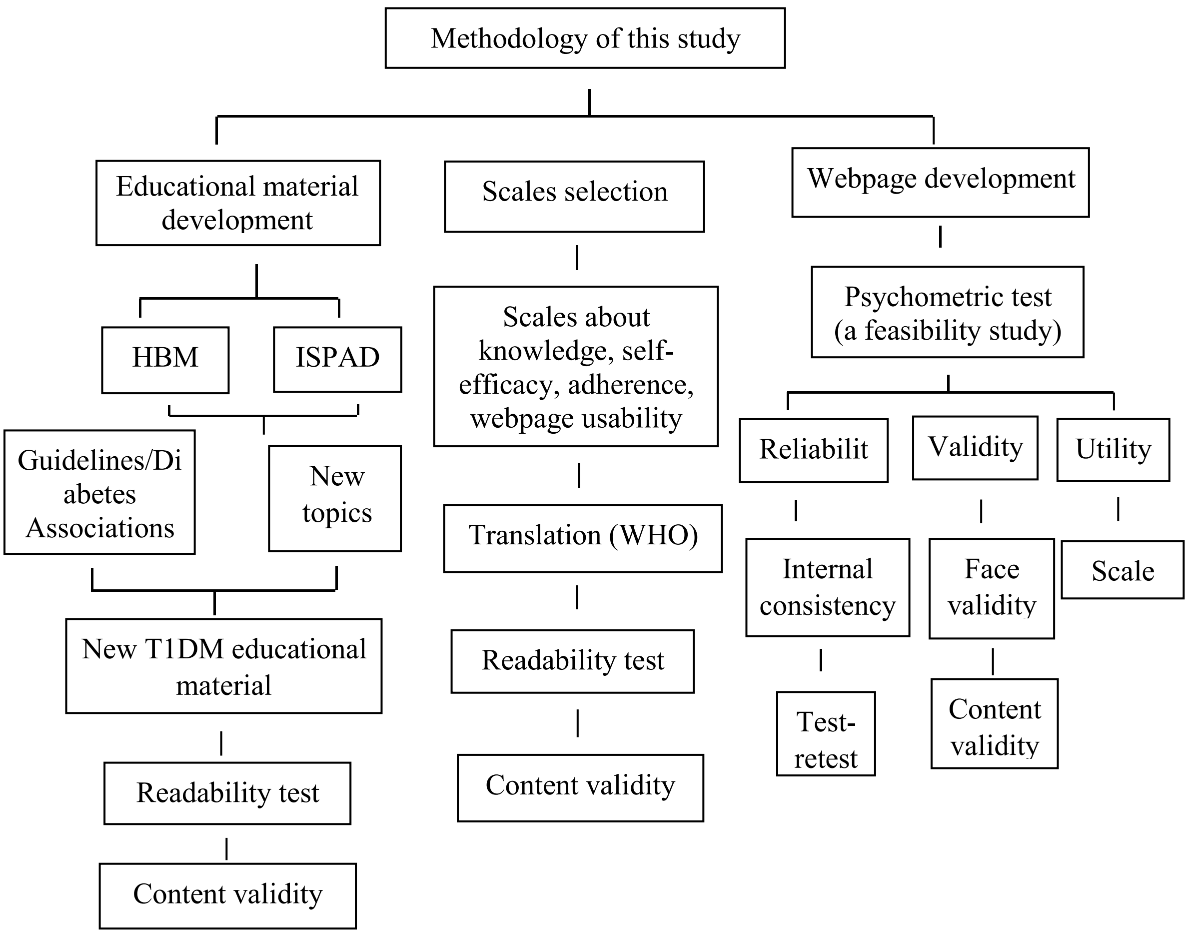


Fig 4.1. Flow chart of the methodology of this study

4.1. Design of a web-based T1DM educational material among adolescents

4.1.1. Why was a web-based type 1 diabetes educational material developed?

The International Society for Pediatric and Adolescent Diabetes (ISPAD) Clinical Practice Consensus Guidelines 2018 recommend the use of new technologies to motivate children and adolescents to take part positively in diabetes care and education. Internet-based diabetes education adds the benefit of easier access for individuals, including those in remote areas (Phelan et al., 2018). However, according to the systematic review in chapter two, there has been only one RCT exploring the effects of web-based diabetes education on Chinese adolescents with T1DM.

According to the China Internet Network Information Centre (CNNIC), 85.3% of children and adolescents at the age of 6-24 years browsed the internet in 2015 (CNNIC, 2016). The popularity of the internet with children and adolescents provided the possibility of web-based diabetes education. However, little validated diabetes educational material was specific for adolescents with DM in China.

4.1.2. Purpose of the T1DM educational material

The purpose of the web-based type 1 diabetes educational material was to improve DM knowledge, self-efficacy and adherence among adolescents with T1DM.

4.1.3. Content development of the T1DM educational material

In China, there has been no systematic DM education guideline specifically for children or adolescents. Although the Chinese health education centre released seven brochures about diabetes education in 2018, the brochures were hard for children and adolescents to understand. The reasons included:

- The brochures were developed for adults with type 1 and type 2 diabetes, which included oral hypoglycaemic medicines, rather than specifically for children or adolescents with T1DM;
- Many medical terminologies were involved without further explanation, such as DKA, anaerobic exercise; there has been no report exploring the readability of the seven brochures;
- Some contents would be beyond of adolescents' ability to learn and understand, such as differences between second-generation and third-generation insulin;
- There were no studies testing content validity of the brochures and whether the brochures were effective to improve patients' knowledge;

Therefore, evidence-based diabetes educational material was specifically developed for Chinese adolescents (10-19 years) with T1DM in this study.

Translation of ISPAD guideline 2018

The Health Belief Model (HBM) provided the theoretical framework for the T1DM educational material during the content development process. The ISPAD Clinical Practice Consensus Guidelines 2018 Compendium (DiMeglio et al., 2018) reported basic principles and systematic education topics specifically for children and adolescents. The principles and topics were involved in the development of the material.

ISPAD Clinical Practice Consensus Guidelines 2009 and 2014 were translated into other languages, such as Polish and Russian. ISPAD Clinical Practice Consensus Guidelines 2018 were published in October 2018 when the T1DM educational material in this study begun to be developed and there was no translated Chinese version existing at that time. After getting permission from the ISPAD to translate the Chapter 6 "Diabetes Education in children and adolescents" into Chinese, the translation process included five steps, consisting of forward translation, expert panel, back translation, pre-testing and cognitive interviewing, and repeating the above steps to get a satisfactory version (WHO, 2018b).

Process and principles to edit the specific contents of the material:

(1) The process of editing the T1DM educational material was as follows:

- The education topics from the ISPAD guideline 2018 were integrated into the six core constructs of HBM, which formed new education topics of the T1DM educational material.

- Furthermore, diabetes associations' websites, diabetes guidelines and some high-quality articles provided references for the specific contents of the new topics, which were helpful to improve content validity of the T1DM educational material.

(2) The basic principles of editing the T1DM educational material were as follows:

- The contents were systematic and scientific;

- The contents were developed as simple as possible and suitable for adolescents;

- Different strategies were used to deliver the contents to attract adolescents' interests, including cartoon story, images, tables, and questions and answers.

4.1.4. Testing of the web-based T1DM educational material

Testing of the web-based T1DM educational material is mentioned briefly here. Readability of the material was tested to explore if adolescents can understand it. Content validity was also used to test if contents of the T1DM educational material were scientific and clinically accurate.

4.2. Selection, translation and testing of the questionnaires

As mentioned, the study aimed to improve diabetes knowledge, self-efficacy and adherence among adolescents and test usability of the webpages developed in this study. The four aspects of outcomes were measured through scales. Therefore, selection of the scales in Chinese or English, translation of English scales, and the testing are mentioned briefly in this part.

4.2.1. Selection of questionnaires

Questionnaires were selected according to the following standards:

- Scales were developed or tested to be suitable for adolescents with T1DM;
- No items were unsuitable for adolescents;
- It was easy for younger adolescents to understand and complete;
- Scales had been tested to be reliable and valid among adolescents with T1DM;
- About language, validated scales for Chinese adolescents with T1DM were preferred; if not, English scales were selected.

After searching and comparing between scales, three scales, including the Self-efficacy in Diabetes Management (SEDM), the Self-Care Inventory scale (SCI) and the System Usability Scale (SUS), were selected to test self-efficacy, adherence and webpages' usability, separately. There were no diabetes knowledge scales meeting the selection standards, and a new scale "Type 1 Diabetes Knowledge Scale" was developed in this study.

4.2.2. Translation of the questionnaires

The four scales, the Type 1 Diabetes Knowledge Scale (self-developed), the Self-efficacy in Diabetes Management (SEDM), the Self-Care Inventory scale (SCI) and the System Usability Scale (SUS) were developed originally in English, which needed to be translated into Chinese because the target participants of the study are Chinese adolescents. The translation was conducted according to the WHO translation and adaption framework (WHO, 2018b).

4.2.3. Reliability and validity testing of the questionnaires

After selection, development and translation of the scales, internal consistency (Cronbach's α), test-retest reliability (the Intraclass correlation coefficient, ICC) and content validity (content validity index, CVI) were used to test the reliability and validity of the four questionnaires among adolescents with T1DM in this study.

4.3. Webpages development

Two experienced engineers were invited to design the webpages together with me in this study. The webpages were designed based on the constructs of the T1DM educational material, which also should be suitable for adolescents to use. Although I did no design the technology of the webpages, the formats and contents on the webpages were my own work, and the engineers undertook the programming only.

4.4. Testing of reliability, validity and utility of the webpages

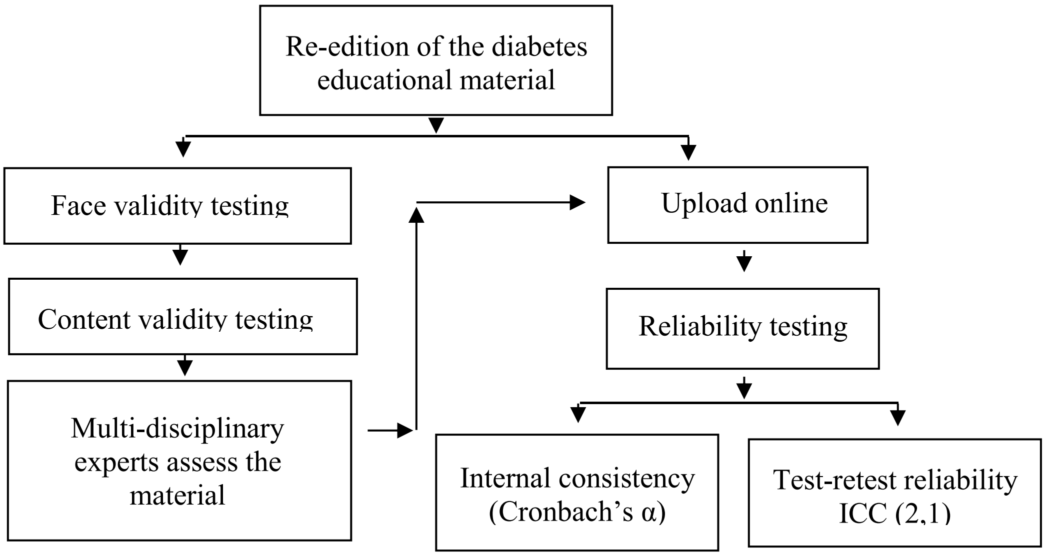


Fig 4.2. Flow chart of reliability, validity testing proposal of the webpages

4.4.1. Reliability testing of the webpages

Internal consistency

Internal consistency is used to evaluate whether groups of items measure different aspects of the same characteristics (Bannigan and Watson, 2009). As mentioned in figure 4.2, all the participants were asked to complete the Type 1 Diabetes Knowledge Scale (self-developed), the Self-efficacy in Diabetes Management (SEDM), the Self-Care Inventory scale (SCI) before and after interventions. For every questionnaire, Cronbach's α (or coefficient α) was used to measure the internal consistency.

Test-retest reliability

Test-retest reliability is assessed by conducting the same testing with the same participants at two different time points. As mentioned in Figure 4.2, the specific process included:

- The type 1 Diabetes Knowledge Scale, the Self-efficacy in Diabetes Management (SEDM), the Self-Care Inventory scale (SCI) were completed by the participants after interventions.

- It is reported that 2 weeks to 1 month is generally acceptable for test-retest (Waltz et al., 2005). Therefore, two weeks later, the same participants of this study were invited to complete the questionnaires again.

- Intraclass correlation coefficient (ICC) was selected to evaluate correlation of the two scores at two time points. According to an article (Koo and Li, 2016), the model "two-way mixed effects, absolute agreement, and single rater" was selected to calculate ICC for the test-retest reliability.

4.4.2. Validity testing of the webpages

A 'test' has validity if it measures what it claims to measure (Bannigan and Watson, 2009). It has been proposed that all types of validity fall under the heading of construct validity (DeVon et al., 2007). Criterion validity was excluded because there were no reliable and valid scales to be used among Chinese adolescents. Factorial validity was also excluded because this is a feasibility testing and the sample size was too small to conduct factorial validity, which will be tested in the main study at next stages. The validity testing included:

Face validity

It was reported that people from different groups related to the subjects need to be involved in the face validity testing (Bannigan and Watson, 2009). In this study, adolescents from different age groups, endocrinologists and diabetes nurses were involved to test if the contents of web-based T1DM knowledge material and scales were appropriate for target participants.

Content validity

In this study, contents of the webpages need to be checked to ensure they are scientific, and consistent with the purpose. The specific process included two stages:

1) Development stage:

- Existing diabetes education contents and scales were searched through systematical review of articles, which provided reference for development of the webpages. In addition, the readability of the T1DM educational material and scales was tested among 10-19-year adolescents.

2) Judgement stage:

- First, regarding number of experts were required to assess content validity, a study reported a minimum of five experts and fewer than 10 (Lynn, 1986), and another study suggested a minimum of seven (DeVon et al., 2007). Therefore, in this study, a panel of 10 experts was organised to evaluate content of the webpages;

- Second, an evaluation form was developed by me and used to guide experts to assess whether the webpages were scientific and consistent with the aims of the material to improve knowledge and confidence of DM management. Contents of the new-developed Type 1 Diabetes Knowledge scale were also be assessed to test whether every item was relevant.

4.4.3. Utility testing of the webpages

The utility of the webpages was tested by using the System Usability Scale (SUS), which was also translated and tested the reliability and validity.

4.5. Feasibility testing of the web-based T1DM education among adolescents

4.5.1. What is a feasibility study?

Generally, clinical trial feasibility testing is a process of evaluating the possibility of conducting a clinical programme in a particular geographical region with the overall objective of optimum project completion in terms of time, targets and cost (Rajadhyaksha, 2010). Simply, feasibility studies are pieces of research done before a main study to answer the question "Can this study be done?", rather than a finial study.

4.5.2. Why is a feasibility study conducted?

The original idea of this study was to develop an effective education program to help adolescents with T1DM manage their diabetes through new technologies. The proposed study method was a randomised controlled trial or a pre-test and post-test study. However, a feasibility testing study was conducted for following four reasons:

1) According to what we know, this was the first time a web-based type 1 diabetes education for adolescents was conducted in the Southwest of China, although similar interventions were conducted in many other countries (Zhao et al., 2017);

2) In terms of the contents, the development of a type 1 diabetes educational material and the webpages is an innovative work for me as I had no prior experiences. Development of webpages needs the involvement of engineers who specialise in webpage development, which is also an external variable factor for the study;

3) Recruitment of adolescents (10-19 years) was also a challenge for this study. Incidence of type 1 diabetes in adolescents at the age of 10-19 years is relatively low (IDF, 2017). In addition, some schools, including some primary, middle and high schools, have regulations that students are prohibited from using mobile phones during

school time. Adolescents usually can have a free access to a computer or have their own laptop in the university in China;

4) Limited time and limited financial support were also part of the reasons to conduct a feasibility study for me as a PhD student.

4.5.3. Study design

A feasibility testing study was conducted, which was registered on the webpage of Centre for Open Science (COS) with the hyperlink https://osf.io/wsvha/links. What was tested in this feasibility study?

1) Whether the research design at the preparation stage was feasible, including the development and validity testing of the type 1 diabetes material and the webpages, selection and translation of the scales;

2) Whether the research design at the completion stage was feasible, including participant recruitment and retention, and reliability testing of the webpages;

3) Estimation of some important parameters would contribute to the final study, such as standard deviation of outcomes to estimate sample size, number of eligible participants, recruitment rate, follow-up rate, and time needed to collect data;

4.5.4. Ethical approval and ethical considerations

- Ethical approval

In April 2019, the study was approved by the Faculty of Health Sciences (FHS) Research Ethics Committee in University of Hull (reference number was FHS122) and by the Ethics Committee of the Affiliated Hospital of Southwest Medical University in Luzhou (reference number was KY2019020). The approvals are attached in Appendices 4 and 5. Moreover, a substantial amendment was submitted to the FHS Research Ethics

Committee in Hull, which was approved on 12 of June 2019 and is attached in Appendix 6.

- Ethical considerations

1) During the development of the educational material for adolescents, some content in the material could upset adolescents, such as the chronic complications. To prevent or reduce the mental harm happening to the participants, first, I tried to present the related contents in positive ways, rather than negative ways to upset participants. Second, the content in the material was also discussed by expert panel before participants could read it. I also reminded participants to consult their doctors if they did worry about any aspects of the material.

2) During the participant recruitment, participants were informed clearly, easily and completely about the study. For participants who were adolescents, especially for these younger than 18 years old, the participants were involved in the study until both adolescents themselves and their parent had given the consent at the same time. Participants and/or parents were told clearly that they had the right to decline participation of this study, and they could quit at any time if they prefer, which would not affect any diabetes treatment and care in the health system.

4.5.5. Participants and recruitment

Participants in this study were adolescents who met the diagnosis criteria of the WHO for T1DM and had been diagnosed with T1DM (WHO, 2006). Participants were recruited from the Affiliated Hospital of Southwest Medical University, which is a university hospital and a National Class A Grade Ⅲ Hospital in Luzhou situated in the southwest of China. The Chinese hospital system is a 3-tier system (Grades Ⅰ, Ⅱ, Ⅲ), which is further subdivided into 3 levels (A, B, C). In addition to a special level (no hospitals have yet been placed in this level), Class A Grade Ⅲ is the highest ranking in the hospital system in China. The hospital in Luzhou is a general hospital, which contains 3200 open ward beds. In 2019, there were more than 1.8 million outpatients and 140,000 inpatients in this hospital. All the participants recruited in this study would have been inpatients or outpatients of this hospital.

1) Inclusion criteria:

Adolescents with T1DM at the age of 10-19 years old; could understand, speak and read Chinese; had access to phone/computer and internet, and knew how to use a mobile phone or a computer; for adolescents who were younger than 18 years at least one of their family members agreed to their participation.

2) Exclusion criteria:

Those who had been diagnosed with gestational diabetes or had visual impairment which affected diabetes knowledge learning or communication were excluded;

3) Selection of recruitment methods:

According to the China Internet Network Information Centre (CNNIC), more than 800 million people were reported to use smartphone by June 2019 (CNNIC, 2019a). Around 169 million minors (<18 years) accessed internet in 2018, and 92% of them used phones to access internet (CNNIC, 2019b). Therefore, text message or phone call were considered to be appropriate to recruit participants in this study.

4) The process of participant recruitment was conducted as follows:

First, following ethics permissions, the hospital records of the endocrinology and pediatric departments for the last 12 months were searched. The records of patients who potentially met the inclusion criteria were screened and added to an Excel® spreadsheet, which were kept on the Trust computer and confidential. As a member of staff with permissions from the hospital this was possible to achieve.

Second, a text was sent to the potential participants because text is the most popular way to communicate with strangers in China and it was not too coercive.

Third, if fewer than 30 patients respond, more records were searched further and so on.

Fourth, I took responsibility for participant recruitment. Adolescents and parents were given one week to decide whether to participate in the study. Once consenting to take part in the study, participants and one of their parents were asked to sign the consent form. Then participants were taught how to open an account, use the websites and finish questionnaires online.

4.5.6. Sample size

According to a review, there was no need for a formal sample size calculation (Thabane et al., 2010). Based on the results of included studies in systematic review in chapter 2 and another meta-analysis in adolescents with T1DM (Quirk et al., 2014), 20-30 adolescents with type 1 diabetes were projected to be recruited in this feasibility study.

4.5.7. Implementation

After given the hyperlink, recruited participants created their own account on the websites. The webpages were password-protected and only participants knew their own passwords, which was beneficial to protect their privacy. As shown in Figure 4.3, all participants were invited to finish three scales about T1DM knowledge, self-efficacy and adherence in the first part, then read a T1DM educational material in the second part, and complete four scales in third and fourth part of the webpages. The final part needed to be completed two weeks after the third part was finished. If they had any problems with using webpage, they could contact the engineers through a phone number.

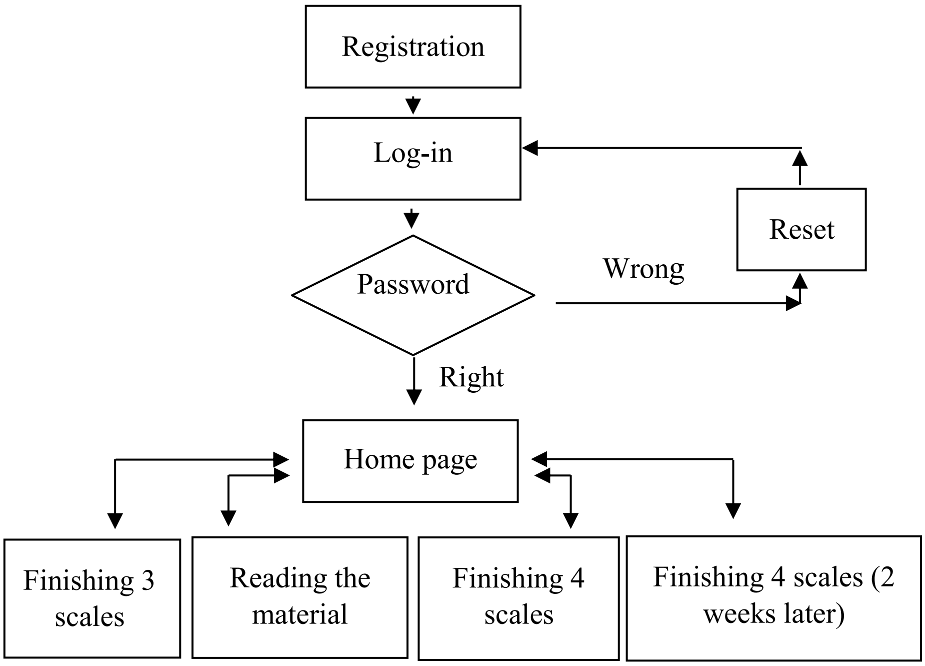


Fig 4.3. Flow chart of webpages usage in the feasibility study

4.5.8. Data collection

Adolescents were invited to complete the scales online after they consented to take part in the study, and parents also gave consent when their children were younger than 18 years. The process of data collection was completed on the self-developed webpages in this study. Demographic characteristics of participants were recorded when they registered on the webpages, such as gender, education background, age and diabetes duration.

Outcomes consisted of four scales, including self-developed Type 1 Diabetes Knowledge (T1DK) scale, the Self-efficacy in Diabetes Management (SEDM), the Self-Care Inventory scale (SCI), the System Usability Scale (SUS). The adolescents were invited to complete the outcome measures at three time points, that was before reading the type 1 diabetes educational material (“Pretest”), after reading the material (“Post-test”) and two weeks later (“Retest”).

4.5.9. Measures and data analysis

(1) Recruitment rate

Recruitment rate will be calculated by dividing the number of all eligible participants by the number of those registered on the webpages. A recruitment rate of between 25% and 40% would be considered reasonable (Quirk et al., 2014). Reasons for not meeting the eligibility criteria, barriers and facilitators to recruit participants were also analysed.

(2) Data completion rate

The completion rate of four parts of the webpages was recorded completely or partially. It would be acceptable if more than 70% are fully completed (Blake et al., 2016). Reasons for not completing the study and barriers were analysed.

(3) Utility of the webpages

The System Usability Scale (SUS) was used to test webpages usability. There were two kinds of methods to assess usability of the webpages. First, mean and standard deviation (Mean ± SD) of each item was calculated in the SUS scale. Second, descriptive statistics was another way to assess the webpage usability. SUS score≤50.9 was OK, ≤71.4 was good, ≤ 85.5 was excellent, and ≤100 was best imaginable (Bangor et al., 2008).

(4) The differences of diabetes knowledge, self-efficacy and adherence before and after studying the T1DM educational material

In order to preliminarily test whether the web-based T1DM educational material is beneficial to improve adolescents’ diabetes knowledge, self-efficacy and adherence, paired t-test was used to test whether the differences of diabetes knowledge, self-efficacy and adherence before and after reading the material are significant. If $P<0.05$, the results were recognised as being statistically significant.

CHAPTER 5 DEVELOPMENT OF TYPE 1 DIABETES MATERIAL

The type 1 diabetes educational material is the core content for adolescents in this study, which is also an innovative tool for Chinese adolescents aged from 10-19 years. The material was developed through four stages as shown in Figure 5.1, including preliminary development in English, forward and backward translation, readability testing, and content validity testing.

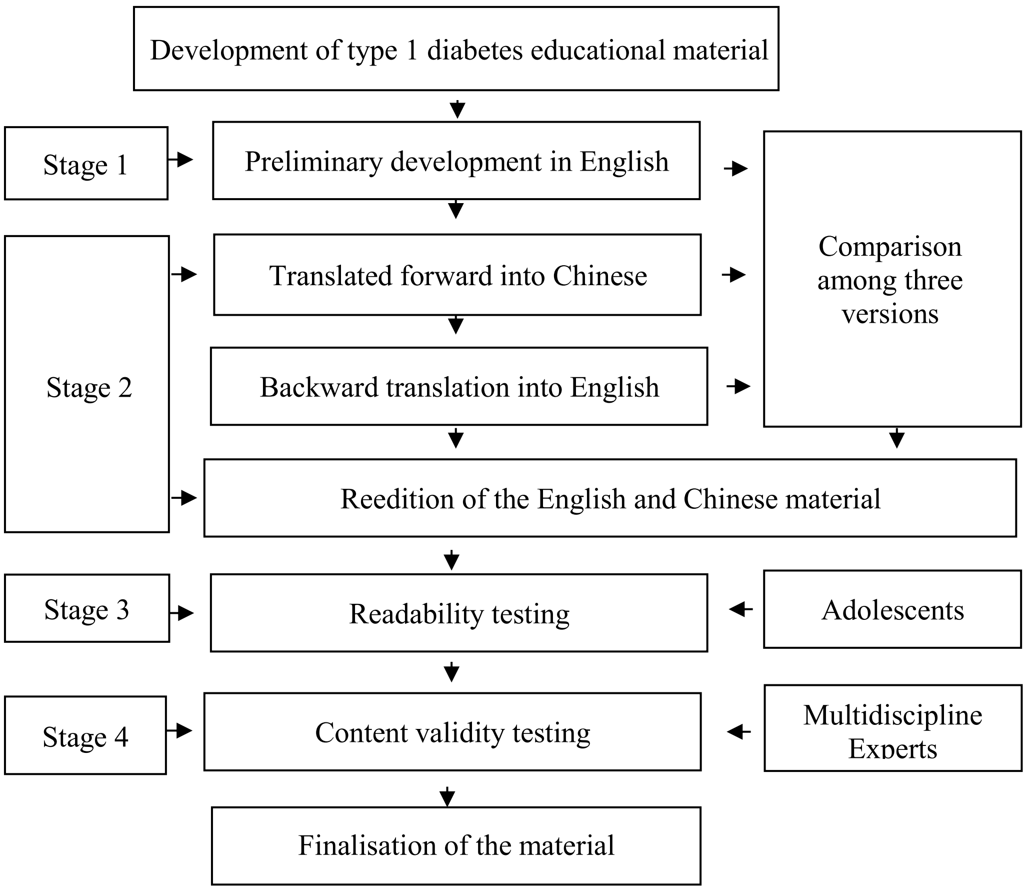


Fig 5.1. Development process of the type 1 diabetes educational material

5.1. Stage 1 (9/2018-12/2018): Preliminary Development in English

5.1.1. Basic introduction

Before and during editing the T1DM educational material, basic principles need to be made according to purposes of the material and target populations. This material is specifically developed for adolescents with T1DM at the age of 10-19 years with the aim to improve their diabetes knowledge, self-efficacy and adherence of diabetes management. Therefore, the basic principles throughout the whole development process included:

(1) The material is assessed to be scientific and clinically accurate. Therefore, diabetes guidelines (such as ISPAD), diabetes associations websites (such as Diabetes UK, American Diabetes Association), and some referenced peer viewed critically appraised articles provided references for the T1DM educational material.

(2) To improve adolescents' self-efficacy, the material also included some common psychosocial problems adolescents may meet at home or school, in addition to diabetes knowledge and skills.

(3) To attract adolescents' interests, multiple designs, including cartoon story, images, stories, questions and answers, and quizzes, were used to make the material easy to understand and interesting.

5.1.2. Steps taken at this stage

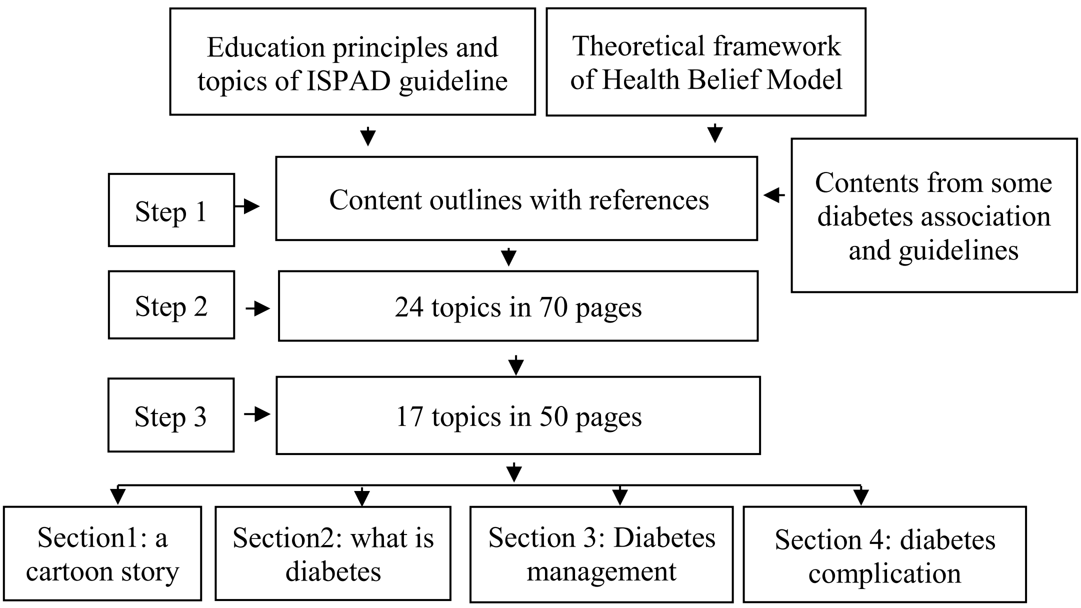


Fig 5.2. Flow chart of the preliminary development process of the material

The material was developed preliminarily through three steps, including developing content lists or outlines, edition of specific contents with 24 “topics”, and refinement of contents into 17 “topics”. The details were summarised as follows:

Step 1 (9/2018-10/2018): Developing content lists or outlines

At this step, an important issue was to assure that the content outlines were comprehensive and systematic, and included basic knowledge that every adolescent with T1DM should know. The theoretical framework of Health Belief Model (HBM) and systematic education topics of the International Society for Pediatric and Adolescent Diabetes (ISPAD) Clinical Practice Consensus Guidelines 2014 and 2018 Compendium (Lange et al., 2014, DiMeglio et al., 2018) made a major contribution to the content outlines of the T1DM educational material in this study. In addition, some psychosocial topics were also added after searching some medical databases, such as Pubmed and EBSCO. Preliminarily, the content outlines included primary education (level 1) with 21 “topics” and continuing education (level 2) with 18 “topics”, as mentioned in the ISPAD guideline 2014.

Step 2 (10/2018-11/2018): Edition of detailed contents with 24 “topics”

At this step, it was important to ensure that the detailed contents of the material were scientific and clinically accurate. Therefore, diabetes guidelines and associations websites were searched to provide references for every “topic”. There were 24 “topics” with more than 70 pages edited according to the guidelines, such as the ISPAD (Lange et al., 2014, DiMeglio et al., 2018) which are specifically for children and adolescents with diabetes and “A toolkit to inform on diabetes in school” (IDF, 2018), some diabetes associations, such as Diabetes UK and American Diabetes Association, and some articles from medical databases.

Step 3 (11/2018-12/2018): Refinement of contents into 17 “topics”

At this step, the contents were refined, including deleting duplicated contents, and fixing the format (i.e. ensuring consistency) of every “topic”. Finally, 17 “topics” were kept in the material, which were divided into four sections, including a cartoon story (1 “topic”), "what is diabetes” (4 “topics”), diabetes management (7 “topics”), diabetes complications and prevention (5 “topics”). Every “topic” was edited with five fixed formats, including “key knowledge point”, “introduction”, “frequently asked questions”, “a quiz” and “references”. The whole edition process was summarised below in Table 5.1.

Table 5.1. The edition process of the type 1 diabetes educational material

Constructs of HBM	Application introduction	Education topics in the ISPAD 2014	Orders of content outline	Topics in the material
Perceived Susceptibility	1. Define populations at risk, risk levels; 2. Personalise risk based on a person's characteristics; 3. Make individuals notice their actual risk.	Epidemiology and risk factors of T1DM and complications;	Level1-1; Level2-1;	Section 4 (2.2-2.3)
Perceived Severity	1. Specify consequences of risks and conditions; 2. Trigger emotions like distress and regret with images;	1. Physical: complications and symptoms; 2. Emotional: some common emotional reactions and solutions;	Level1-3,5,20; Level2-1,2,12,13,14;	Section 4 (4.1-4.3)
Perceived Benefits	1. Shift perspective by highlighting others' belief and effects; 2. Provide knowledge in favour of the behaviour;	1. Introducing some successful stories to encourage participants; 2. Components of DM management and benefits;	Level1-6,7; Level2-3,4;	Section1; Section 3 (3.1-3.7); Section 4 (4.5);
Perceived Barriers	Identify and reduce perceived barriers through reassurance, correction of misinformation, incentives and assistance.	1.Misunderstandings about DM management; 2. Physical barrier: insulin resistance; 3. Influences from school; 4. Psychological barriers; 5. Special times;	Level1-4,9,11,14,15,17,19; Level2-1,10,11,16;	Section 2 (2.1); Section 3 (3.6-3.7);
Cues to Action	1.Promote awareness; 2. Use appropriate reminder and recall systems	1. Introducing stories to encourage them; 2. Seek support from peers/family;	Level1-6,18; Level2-4,17;	Section1; Section 3 (3.7); Section 4 (4.5);
Self-Efficacy	1. Provide guidance in performing the recommended action; 2. Use progressive goal setting; 3. Give verbal reinforcement; 4. Demonstrate or model desired behaviours; 5. Reduce anxiety about acting;	1. Learning more DM knowledge; 2. How to deal with psychological reactions; 3. Learning practical diabetes skills; 4. Encouraging participants by telling others' successful stories;	Level1-8,10,12,13,16,21; Level2-3,5,6,7,8,9,15,18;	Section1; Section 2 (2.1, 2.4); Section 3 (3.1-3.7); Section 4 (4.1-4.5);

5.1.3. Results

Section 1: A day in the life of Xiaobei, living with type 1 diabetes (a cartoon story)

A cartoon story was involved in this section, which aimed to attract adolescents' interests at the beginning of the material. The cartoon story was adapted from the 'Tom's story' of the educational material "A toolkit to inform on diabetes in School", which was developed by the International Diabetes Federation for kids, teachers and parents (IDF, 2018). Tom's story described a day of Tom who was a boy with T1DM at school and home, which was presented in Appendix 7.

However, it was not appropriate, directly, to put Tom's story in the material of this study because of some culture differences. For example, person's characteristics, food and housing were based on Western countries, which were totally different from China and may cause confusion among Chinese adolescents. Therefore, Tom's story was adapted into a new Chinese cartoon story which was titled: "A day in the life of Xiaobei, living with type 1 diabetes". It also described Xiaobei's meals, blood sugar monitoring, insulin injection and exercise during a school day. Xiaobei's story was designed by me and drawn by a first-year nursing student in Southwest Medical University, which was presented in Appendix 8.

Section 2: What is diabetes?

This section consisted of four "topics". The definition of DM was described by using simple words and images in three "topics". In another "topic", adolescents' feeling after diagnosis was also presented by designing the conversations between presumed adolescents with T1DM. The presumed characteristics were set as Chinese persons who were involved in the whole material. The presumed roles included six adolescents at the age of 10-19 years, a nurse, a dietician, an endocrinologist, and a psychologist as shown in Figure 5.3.

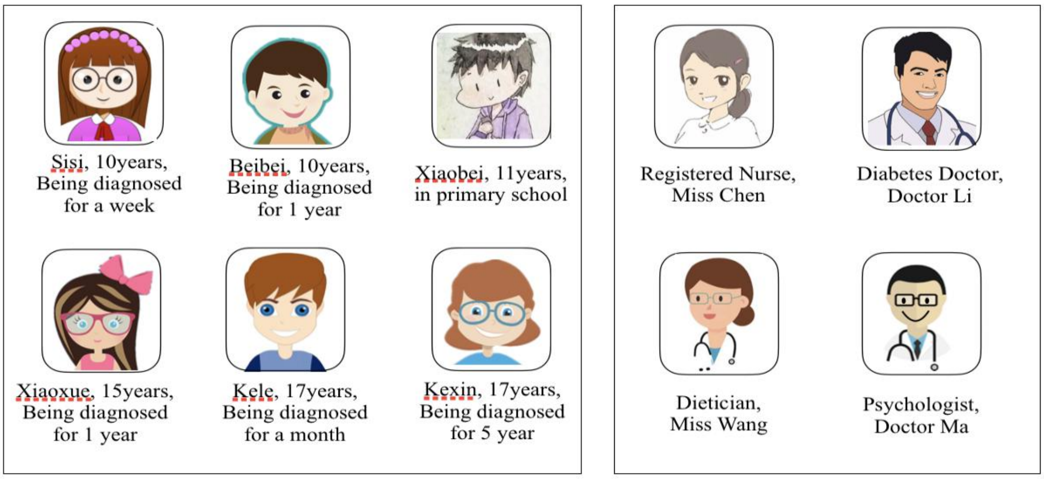


Fig 5.3. Presumed characteristics of the type 1 diabetes educational material

The images and presumed characteristics in this material came from the Internet and were reedited to suit the material. An essential issue I met was copyright of the images from internet. In order to follow the Copyright and Rights in Performance (Research, Education, Libraries and Archives) Regulations 2014 and respect of the copyright-protected works, the images and presumed characteristics were searched from copyright-free websites, such as Pixabay, or Google Chrome where the images were labelled for reuse.

Section 3: How to manage type 1 diabetes

Seven "topics" were designed in this section, including diabetes knowledge and food (a "topic"), exercise and insulin treatment (a "topic"), insulin injection technology (two "topics"), blood sugar testing (a "topic"), "how to manage diabetes when you are ill" (a "topic") and "how to deal in relationship with schoolmates at school" (a "topic").

Section 4: Diabetes complications and how to prevent

Five "topics" were kept, including low blood sugar and prevention (a "topic"), high blood sugar and prevention (a "topic"), long-term complications (a "topic"), prevention of long-term complications (a "topic"), and "diabetes does not affect your future" (a "topic"). To encourage adolescents to insist on their diabetes management, the last "topic" was a story which was adapted from a true story about a man who had lived well with T1DM for nearly 60 years.

An important ethical issue was considered in this section. Some contents about complications in the material may frighten adolescents, such as retinopathy with potential blindness and neuropathy with risk of amputation. In consideration of the target population, these contents about potentially severe diabetes complications were described positively, for example in following way: "If your blood sugar levels can be controlled well, eye complications can be reduced or avoided".

5.1.4. Impact on the next step

This stage was important because the framework and contents of the material were built. If the editing of the material can be compared to house building, this stage was like design and construction. In the following stages, more interior decorations will be needed.

5.2. Stage 2 (1/2019-3/2019): Translation of the type 1 diabetes educational material

5.2.1. Basic introduction

The T1DM educational material was originally developed in English for several reasons. First, most references in the material were in English, which made it easier to edit an English material. Second, content validity was also planned to be tested among experts in the UK. Third, the material needed to be submitted to the Ethics Committee in the UK to get ethical approval for the research. However, the material was developed for Chinese adolescents. Therefore, the English material was translated forward into Chinese and backwards at this stage.

5.2.2. Steps taken at this stage

According to the WHO's translation framework, translation of the material included forward translation, back translation and comparison among three versions (WHO, 2018b), which are presented in following three steps.

Step 1 (1/2019-2/2019): Forward translation of the material

According to the WHO's translation guidelines, I could be a suitable translator to perform the forward translation because I am a health professional and familiar with terms of the material. I have lived in the UK for two years and have got to know the English-speaking culture, and my mother tongue is Chinese, which was the target language of the material. Therefore, the forward translation of the material was conducted by me (WHO, 2018b).

Some principles were insisted on during the whole process of translation. First, the translation should be conceptual equivalent of a word or phrase, not a word-for-word translation; Second, the translation should be simple, clear and concise; Third, translation should avoid medical terms with consideration of age applicability (WHO, 2018b).

Step 2 (2/2019-3/2019): Backward translation of the material

The back translators should be persons who are not familiar with the material, but know English very well (WHO, 2018b). Considering that the material was more than 50 pages, it could have been too big a challenge for one person to undertake the backward translation. Therefore, the material was divided into four parts, which were translated backwards into English by four colleagues of mine. The four persons' mother tongue was Chinese. Their lowest degree was bachelor, and they had no knowledge of the material before backward translation and acted voluntarily.

An introduction and the principles of back translation were also sent to the four persons, as well as a selected part of the material. A month was given for the volunteers to return the backward translation to me. Details are presented in Table 5.2.

Table 5.2. Details of people conducted backwards translation of the material

Code	Age (years)	Education background	Contents translated backward in the material
CT01	30	Biologist, PhD in the UK	Introduction page; section 2 (2.1-2.4)
CT02	30	Registered nurse, PhD student in Macao	Section 3 (3.1-3.4)
CT03	24	Registered nurse, Mater student in nursing in China	Section 3 (3.5-3.7), section 4 (4.1)
CT04	33	Engineer, Master degree in China	Section 4 (4.2-4.5)

Step 3 (3/2019): Comparison among three versions of materials

This step aimed to check whether the Chinese version (CV) had exactly the same meaning with the original English version (EV1). The back translated version (EV2) was compared with the original English version (EV1) by me and both supervisors who are native English speakers. The Chinese version was checked by me with EV1 and EV2. There were two kinds of problems found among the translation process and corresponding solutions were summarised in Table 5.3.

Table 5.3. The problems and solutions during translation of the material

Order	The problems	How to deal with
1	Extra words or sentences were added in the back translation, compared to the original version.	• The Chinese version was checked. • Compared to the original English version (EV1), several words were added in the Chinese version (CV) to make the meanings more accurate in Chinese. • Try to keep the Chinese and original versions (EV1) consistent, including adding some words in the original version (EV1) or deleting some cumbersome words in the Chinese version (CV);
2	Some words in the back translated version (EV2) had different meanings compared with the EV1.	• EV1, EV2 and the Chinese version were re-checked. • According to supervisors' suggestions, the words were found and modified properly in EV1 or EV2.

5.2.3. Results

At this stage, the English version of T1DM educational material was translated forwards into Chinese, which was also ensured to have the same meanings with the original English version through backward translation and comparison between different versions of the material.

5.2.4. Impact on the next stage

Age applicability was considered throughout the translation process, such as using words as simple as possible and explaining medical terms in words adolescents could understand by "standing in adolescents' shoes", which may be also a way to improve readability of the material at next stage.

5.3. Stage 3 (3/2019-4/2019): Readability testing

5.3.1. Basic introduction

Readability is used to measure the ease with which a reader can understand a written material, which is important to make a difference between success and failure of the education goal. It indicated a large gap between the required reading level to understand the health information and the actual readability among patients (Daraz et al., 2018). A readability gap was also reported between educational materials and children's actual reading levels (Grootens-Wiegers et al., 2015). Therefore, readability testing of educational materials cannot be emphasised enough.

In English, five readability assessment formulae can be used to assess the readability of materials, including the Flesch-Kincaid Grade Level (FKGL), the Flesch Reading Ease (FRE), the Gunning-Fog Score (GFS), the Coleman-Liau Index (CLI), and the Simple Measure of Gobbledygook (SMOG) index. Microsoft Word is an easily accessible and free tool to calculate the readability scores in English. In this study, through the Microsoft Word, Flesch reading ease of the T1DM material in English was assessed to be 75.8, and Flesch-Kincaid grade level was 5.6. This meant the English-version T1DM material was fairly easy to read. However, different from English, researches on readability assessment of Chinese materials are still in initial stage because of complexity of Chinese characters. There have been no automatic tools with accurate prediction ability to test the readability of Chinese (Lau, 2006).

5.3.2. Steps taken at this stage

In this study, the method to assess the readability of the T1DM educational material in Chinese was to recruit adolescents without diabetes to read the material and identify whether there were words, phrases and sentences which they could not understand. At this stage, the recruitment of adolescents, readability testing and result analysis will be described in following three steps.

Step 1 (3/2019): Recruitment of adolescents to test the readability

Adolescents between the ages of 10-19 years old without diabetes were planned to be recruited to test the readability of the material because it was easier to recruit adolescents without diabetes than those with T1DM in China. Finally, seven adolescents without diabetes were recruited through a teacher who was working in a middle school in Luzhou. The information of the seven adolescents are presented in Table 5.4. To protect their privacy, their names are substituted by codes.

Four of these adolescents (CA01-04) were recruited from a school, which was a combination of a primary school and a middle school. Therefore, an informed consent form was drafted to get the permission from the school to test the readability of the T1DM educational material. The informed consent included purpose of the readability testing, what adolescents need to do, and effects on adolescents. Permission of the readability testing was received from the school. Another three adolescents (CA05-07) at the age of 16-19 years were recruited separately and privately.

Table 5.4. Details of seven adolescents recruited to test readability of the material

Code	Age	Gender	Education status
CA 01	11	Female	5th year in primary school in China
CA 02	12	Male	5th year in primary school in China
CA 03	13	Female	2nd year in middle school in China
CA 04	14	Female	2nd year in middle school in China
CA 05	16	Female	2nd year in high school in China
CA 06	17	Female	3rd year in high school in China
CA 07	19	Female	2nd year in the college in China
Notes: In Chinese education system, there are 6 years in primary school, 3 years in middle school, 3 years in high school and 3-5 years in college or university.			

Step 2 (4/2019): Readability testing

After recruitment, every adolescent was given the printed material with an invitation letter from me and a “suggestion page”. Considering the ages of target population, the invitation letter was presented with images and simple words, including brief introduction of material, what they needed to do, the deadline of the task and how to return the material. Specifically, these adolescents were required to circle the word, phrase or sentence they could not understand by using a red marker, and write down their suggestions about the advantages and disadvantages of the material in the "suggestion page". Two weeks were given for them to complete the readability testing. The invitation letter for adolescents to test the readability of the educational material is attached as Appendix 9.

Step 3 (4/2019): Data analysis and synthesis

Both the T1DM educational material and the "suggestion page" were required to be returned. All the seven adolescents completed the readability testing and returned the materials two weeks later. The result of the readability testing, the characteristics adolescents like and things to be improved in the material were analysed by me.

5.3.3. Results

(1) The result of readability testing in the material

Regarding the readability of the T1DM educational material, four adolescents did not mention any words or phrases of the material they could not understand. Another three adolescents marked five medical terms which were difficult for them, including Type 1 diabetes, Diabetic ketoacidosis (DKA), HbA1c, Continuous glucose monitor (CGM), Long-term complications.

No changes were made because the five medical terms were only marked before they read the definition or explanation of the terms. In addition, it was also mentioned that "medical terms were explained in easy-understanding ways" by adolescents in the "suggestion page".

(2) The characteristics adolescents liked in the material

Every adolescent wrote down the advantages and their suggestions for the material. Generally, adolescents evaluated that the material was easy to understand and interesting, which is consistent with original purpose of the material. The advantages are summarised in Table 5.5.

Table 5.5. Summary about what adolescents liked in the type 1 diabetes material

Items	Quotes from adolescents
1) The involvement of cartoon story, combination of words and images, conversations and examples were welcome.	"The cartoon story is simple and intuitive;" "Images help me understand the content;" "The conversations among adolescents and doctors are good, including the questions and answers;" "Combination of words and images, and cartoon story are easy to understand and will win the heart of kids;" "The content is comprehensive, and the format is good;" "Compared with other books, I like the format and language of this book;" "I like the introduction of diabetes causes and reminding people through conversation;" "It is good to use examples to explain some abstract content, which becomes not boring, but interesting and vivid."
2) Some specific contents adolescents like were mentioned.	"The contents about insulin injection in page 27 are good." "The advantages and disadvantages of diabetes (how to manage diabetes and complications prevention) were described clearly;" "The medical terms were explained in easy-understanding ways. Basically, there are no words or sentences which cannot be understood." "I like the content about symptoms of diabetes;"

(3) Some aspects of the material required improvement

Some adolescents also gave their suggestions for the material, which were summarised and given corresponding solutions in Table 5.6. Some suggestions were feasible and adapted at this time. Some suggestions could provide good references for the reedition of the material next time.

Table 5.6. Summary of the improvements of the material adolescents mentioned

Order	Suggestions	Changes made
1	For younger adolescents, the English words (that is "Good afternoon, Mrs. Li") of the cartoon story in section 1 can be changed into Chinese.	No changes; It was set to be an English class and the English words used were easy to understand.
2	Order the cartoon story in section 1.	Good suggestion; No changes this time because it is hard to add for hand-drawing cartoon after finished.
3	In the page "Table of Content" apostrophe can be added between the titles and the pages.	The written version was modified. However, it will not be a problem after uploading to the webpages.
4	Increasing the numbers of the quiz;	Good suggestion; Increased 5 more quizzes in section 2 (2.2, 2.3) and section 3 (3.2, 3.4, 3.5).
5	Increasing stories of adolescents with type 1 diabetes;	Good suggestion; No changes this time;
6	Figures can be used to express some trends, which are clearer and more intuitive;	Good suggestion; No changes this time;
7	Conversations can be increased between characteristics and more characters can be designed.	Good suggestion; No changes this time;
8	Some repeated contents can be deleted;	No changes; There was no any specific content mentioned.
9	The topic "what is type 1 diabetes" in section 2 (2.3) is suggested to be put in section 1, which can help readers understand the material;	No changes; It may be not a problem for adolescents with type 1 diabetes. And the cartoon was put at the beginning, which can attract readers.
10	It is suggested that the factors to cause diabetes and the main population to have diabetes can be increased;	Causes of type 1 diabetes were added simply.
11	Most information is designed for people with type 1 diabetes, and information for the ordinary people can be increased;	No changes this time; It is specifically for adolescents with type 1 diabetes.
12	The comparison between type 1 diabetes and type 2 diabetes;	No changes this time; It is specifically for adolescents with type 1 diabetes.

5.3.4. Impact on the next stage

Readability testing of the T1DM material was an important part, which aimed to assess whether adolescents aged 10-19 years can understand the material. Furthermore, another essential part was to test whether the material was scientific and clinically accurate, which is content validity testing at the next stage.

5.4. Stage 4 (3/2019-5/2019): Face and content validity testing of the material

5.4.1. Basic introduction

For a newly developed tool, psychometric properties need to be tested to identify whether the tool is reliable and valid to be used in certain population (DeVon et al., 2007). Therefore, it was important to ensure that the newly developed educational material was psychometrically sound. As mentioned in chapter 4, face validity and content validity were selected to be tested in the T1DM educational material. In this study, face validity meant testing the grammar, organisation, appropriateness and confirm whether the material appeared to flow logically. Content validity was to test whether contents of the material were scientific and clinically accurate, and the framework of the material was appropriate for adolescents.

5.4.2. Steps taken at this stage

Step 1 (3/2019): Recruitment of experts

Type 1 diabetes management is a comprehensive process for adolescents, where diet and psychological management are important but difficult aspects. Therefore, in addition to endocrinologists and diabetes nurses, a dietician and psychologist were also recruited in the multidisciplinary expert panel to assess the face and content validity of the T1DM educational material. Experts from the National Health Service (NHS) in the UK and a public hospital in China were invited. Finally, six experts from the Affiliated Hospital of Southwest Medical University in China agreed to participate in this study. Information about the six Chinese experts was summarised in Table 5.7.

Table 5.7. Details of six experts in face and content validity testing of the material

Code	Professionality	Education background	Work experiences (years)
CE01	Endocrinologist	Doctor degree	8
CE02	Endocrinologist	Master degree	5
CN01	Diabetes Nurse	Bachelor degree	30+
CN02	Diabetes Nurse	Bachelor degree	30-
CD01	Dietician	Master degree	7
CP01	Psychologist	Master degree	10+

Step 2 (4/2019-5/2019): Two-round face and content validity testing

Two rounds of face and content validity were conducted with six Chinese experts at this stage. In the first-round testing, an invitation email, an evaluation form with introduction, an informed consent form about acknowledgement in the dissertation and potential publications, and the type 1 diabetes educational material were sent to the six Chinese experts who had agreed to take part in face and content validity testing. The evaluation form was sent to experts to assess whether every "topic" in the material was scientific and clinically accurate, whether it aimed to improve adolescents' diabetes knowledge, self-efficacy or adherence, and whether it should be retained in the material. If they had some specific suggestions for the material about grammar or organisation, they could comment on the material. Three weeks were available for the experts to complete this stage. The evaluation form and the material with comments were returned on time to me by all the six experts in the first round. The results will be presented later. The evaluation form is attached as Appendix 10.

In the second-round testing, according to suggestions from the experts in the first-round testing, the educational material was reedited and sent to the six experts again. Three weeks were still available for them. As a result, five experts gave the further suggestions and another one had no more advice.

5.4.3. Results

(1) Evaluation of 17 “topics” in three aspects of the material

First, as shown in Table 5.8, in terms of the scientific and clinical accuracy of the material, 11 “topics” and 5 “topics” were assessed to be or partially be scientific and clinically accurate, separately (but mostly accurate). One expert assessed the “topic” “What is diabetes” to be not scientific and clinically accurate because the content about how to diagnose type 1 diabetes was not accurate, which will be mentioned to be specific in Table 5.9.

Second, 10 “topics” and 7 “topics” were assessed to be or partially be consistent with the purpose to improve diabetes knowledge and confidence to manage their diabetes, separately.

Third, as far as their necessity to be retained, all the “topics” were assessed as “yes” or “partially yes”. Only the cartoon story in the first section was assessed partially to be kept because Xiaobei’s insulin injection site on abdomen was not accurate. All of 17 “topics” were retained after revision according to what experts suggested. The detailed evaluation results were summarised in Table 5.8.

Table 5.8. Content validity evaluation of the material among six experts

Section	Topic	Scientific and clinically accurate			Consistent with the purpose to improve knowledge and confidence			Need to be kept in the material		
		Yes	Partially yes	No	Yes	Partially yes	No	Yes	Partially yes	No
Section 1	1. Xiaobei's A day with type 1 diabetes	5	1	0	6	0	0	5	1	0
Section 2	2.1 How did you feel about diagnosis	6	0	0	6	0	0	6	0	0
	2.2 What is diabetes	5	1	0	5	1	0	6	0	0
	2.3 Type 1 diabetes	4	1	1	5	1	0	6	0	0
	2.4 How does type 1 diabetes make you feel	6	0	0	6	0	0	6	0	0
Section 3	3.1 Knowledge and food	6	0	0	6	0	0	6	0	0
	3.2 Exercise and insulin treatment	6	0	0	6	0	0	6	0	0
	3.3 Insulin injection1	5	1	0	5	1	0	6	0	0
	3.4 Insulin injection 2	6	0	0	6	0	0	6	0	0
	3.5 Blood sugar testing	6	0	0	5	1	0	6	0	0
	3.6 How to manage diabetes when you are ill	6	0	0	5	1	0	6	0	0
	3.7 How to deal with the relationship at school	6	0	0	6	0	0	6	0	0
Section 4	4.1. Low blood sugar	5	1	0	5	1	0	6	0	0
	4.2. High blood sugar	5	1	0	5	1	0	6	0	0
	4.3 Long-term complications	6	0	0	6	0	0	6	0	0
	4.4 Long-term complications prevention	6	0	0	6	0	0	6	0	0
	4.5 Diabetes does not have to affect your future	6	0	0	6	0	0	6	0	0

(2) Suggestions and changes in the content validity testing

In the first-round testing, six experts gave their suggestions, every one of which was considered seriously. The practical suggestions were adopted and reasons were presented if the suggestions were not adopted this time. In the second-round testing, only five experts had suggestions. Suggestions and solutions in the two-round content validity testing were described in Tables 5.9 and 5.10.

Table 5.9. Suggestions in the first-round content validity testing of the material

Experts	Suggestions from experts	The solutions
CE01-Endocrinologist	1. Diagnosis standards (fasting blood sugar >7.0; anytime >11.1) of type 1 diabetes in 2.3 (type 1 diabetes) can be moved to 2.2 (what is diabetes). 2. In 3.4 insulin injection (2-page 27), reuses of needles could increase pain, the risks of infection and lumps (suggested to add). 3. About the HbA1c value (3.5-page30), it is suggested that HbA1c is the most optimal for adolescents with T1DM, and there is no need to mention the suboptimal target (7.5-9) because adolescents need a strict blood sugar control. 4. About low blood sugar in the quiz (4.1-page36,38), if there is any symptom of low blood sugar, test blood sugar immediately; and the symptoms of low blood sugar can be modified as "fast heartbeat, sweating and weakness", which is more typical. 5. Diabetes feet (4.3-page43), "feeling like needing or cannot feel pain" is the symptoms of nerve damage, rather than diabetes feet.	1. No change. It is more systematic if the diagnosis standards stay in 2.3 (type 1 diabetes). 2. Modified as suggested. 3. Modified as suggested. 4. Modified as suggested. 5. The subtitle "Diabetes feet" will be changed into "diabetes feet and nerves damage"

Experts	Suggestions from experts	The solutions
CE02-Endocrinologist	1. (2.2-page9) "for type 1 diabetes, you need to inject insulin all the time because your body can't produce insulin" can be changed into "subcutaneous insulin injection (or under the skin)" 2. (2.3-page 11) About diagnosis of type 1 diabetes, it is not enough to be diagnosed according to blood sugar level. 3. (2.4-page 13)" keep a positive mind and believe diabetes can be controlled well" can be change into "blood sugar" 4. (3.1-page 19) "Apple, cheery, grapefruit, plums and orange contains less sugar than watermelon, grapes, banana and pineapple". (some problems about sugar containing) 5. (4.3-page42) "If you can ……Long-term diabetes complications can be avoided" can be changed into "be reduced or avoided" 6. (4.4-page45) About cause of long-term complications, "because of high blood sugar during a long period of time" can be changed into "because continuous high blood sugar, or with going up and down, can damage blood vessel"	1. Good suggestion; It is more accurate, but may be confusing for adolescents. 2. Modified as suggested. 3. Modified as suggested. 4. Modified; "You can choose the fruits which contain less sugar or raise blood sugar more slowly, such as apple, grapefruit, strawberry, plum, and also need to eat them with limitation." 5. Modified as suggested. 6. Modified as suggested.
CN01-Nurse	1. The title of the material can be changed as "type 1 diabetes educational material". 2. The age limit can be 10-18 years. 3. (2.2-page7) About what is blood sugar, the suggestion is "blood sugar refers to glucose in the blood", rather than "the amount of sugar in our blood" 4. (3.3 subtitle-page24) "Injection process" can be changed into "Injection process by using insulin pen" 5. (3.5-page29) "adolescents with T1DM" (translation problem) 6. (3.5-page30) What is HbA1c, it is suggested to be "HbA1c is the combination of hemoglobin and glucose". 7. (3.5-page30) Definition of Continuous glucose monitor can be changed as "it is a kind of technology to test the glucose change of subcutaneous intercellular fluid through a glucose sensor" 8. (3.5-page31) HbA1c need to be tested every 3 months, rather than every 2-3 months. 9. (3.6 water balance-page33): you can have some drinks with sugar if you have no appetite. (delete "if your blood sugar is falling down 10 mmol/L") 10. (4.1-page37) blood sugar need to be retested after 15 minutes, rather than 10-15 minutes. 11. (4.2 DKA-page39/40) breath smells like rotten apple, rather than rotten fruit. 12. (4.5-page48) the only way to know your blood sugar is to test sugar in the urine? 13. Some words problems (translation of words).	1. Modified as "Educational material for adolescents with type 1 diabetes" 2. No changes. It is the definition from WHO. 3. "Glucose" is too difficult for younger adolescents. Modified as "sugar in the blood". 4. Modified as suggested. This is for adolescents. 5. No changes. This is for adolescent. 6. No change. It is difficult for adolescents. 7. No change. It is too difficult for adolescents. 8. Modified as suggested. 9. No changes. (see ISPAD 2018-sick day management) 10. No change. (ISPAD) 11-13. Modified as suggested;

Experts	Suggestions from experts	The solutions
CN02-Nurse	1. (Page 1) One of 3 purposes to develop the material can be changed into: have good relationships with parents, classmates and friends. 2. (Section1: the cartoon story) The insulin injection site seems like not right. There is a word problem in Chinese when they have dinner in the canteen. 3. (2.1-page6) About the translation of "that's the difference" in Chinese. 4. (2.2-page7) blood sugar refers to the amount of glucose in the blood, rather than sugar. 5. (2.4-page 15) "I write down my blood sugar values", rather than blood sugar level. 6. (3.1-page17) "healthy food refers to a balanced diet, including low in fat, high in fibre, low in added sugar, rich in vitamin and minerals, such as calcium". 7. (3.1-page 18) About food with starch: whole grain food and bean contain low starch, rather than without starch. (Chinese version) 8. (3.2-page21/22) Vigorous exercise is not recommended to people with type 1 diabetes, especially swimming. 9. (4.1-page36) The typical symptoms of low blood sugar should be "Hungry, high heartbeat". 10. (4.2-page 39) For people with DKA, their breath smells like rotten apple, rather than rotten fruit, because rotten apple contains aromatic hydrocarbon, which is ketone body. 11. Suggestions: The contents about food can be described more, for example, how to plan breakfast, lunch and dinner in a day, like carbohydrate counting.	1. Modified as suggested. 2. Modified as suggested. 3. Modified as suggested. 4. No change. Glucose is more accurate, but too difficult. 5. Modified as suggested. 6. Modified as suggested. 7. Modified as suggested. 8. Checked the guideline again and consulted an endocrinologist. It is still controversial (add a guideline about exercise in references). 9. Modified as suggested. 10. Modified as suggested. 11. Good suggestions. Maybe no change this time.

Experts	Suggestions from experts	The solutions
CD01-Dietician	1. (2.2-page7) The definition of blood sugar is not accurate. It can be changed into "blood sugar mainly comes from our food. 2. (2.3-page10) Cause of diabetes is not accurate, except immune system, genetic and environmental factors can also have an effect. 3. (2.3-page11) Translation problem in Chinese: "your body cannot produce insulin to use extra sugar you eat". "use" had been translated into "digest". It was suggested that "deal with" is better. 4. (3.1-page16) "Healthy food with low in fat and added sugar is necessary for everyone with type 1 diabetes". Changed into "low-glycaemic-index diet" 5. (3.1-page 18) 5.1 "You can have healthy sources of carbs foods, such as whole grain food, beans, fruit and vegetables, rather than with starch, such as potato, white rice (suggest to be deleted)" 5.2 Whole grain food and bean contain low starch, rather than without starch (in Chinese version). 6. (3.1-page19) Apple contains more sugar than grapes, but it is still recommended because it is the food with low glycaemic index. 7. (4.1-page 37) About the limit of low blood sugar, it was suggested to be 2.8-3.0 mmol/L (latest Textbook of Internal Medicine in China), rather than 3.9 mmol/L. 8. (4.2-page42) About the limit of high blood sugar, it was suggested to be 11.1 mmol/L (latest Textbook of Internal Medicine in China), rather than 11 mmol/L.	1. Modified as suggested; 2. Modified as suggested; 3. Modified in Chinese (consume one's energy); 4. No change; low-glycaemic-index diet is difficult for adolescents. 5. Modified as suggested; 6. Modified as CE02-4 (contain less sugar or raise blood sugar more slowly). Low glycaemic index is a difficult definition. 7. No changes. It is mentioned that blood sugar value of ≤3.9mmol/L is an alert for adolescents that requires attentions to prevent hypoglycaemia, and a value of <3.0 indicates serious and clinically important hypoglycaemia. (ISPAD 2018) 8. No changes. (ISPAD 2018)
CP01-Psychologist	1. (Chapter 1-the cartoon story): There are 4 times for Xiaobei to test his blood sugar, it is better to add the blood sugar values on the cartoon. 2. (2.1-page5) A suggestion of a better way to translate the phrase "produce a chemical named insulin" in Chinese. 3. (2.4-page13/14) The translation problem, two suggestions of better ways to express. • The first is about "don't care about diabetes", which was suggested to be changed into "focus on diabetes excessively". • The second is about "I always feel inpatient with them", which can be changed into "I always feel inpatient with their excessive concerns, which makes me have a difficult relationship with my parents". 4. (3.5-page 29) About blood sugar monitoring, it is suggested to add the recommended target of blood sugar level ranges. 5. Other suggestions: • The format: The fonts are different; some words are squeezed so that they can't be seen clearly; • Use some bright colour to highlight the "Key knowledge point" in every "topic"; • Put the references at the end of the material because readers can't understand what it is;	1. Good suggestion. No change this time because it is hand drawing and hard to change. 2. Modified as suggested. 3. (2.4-page13/14): • No changes for the first one; In this sentence, it needs a positive phrase, rather than negative one "excessively". • Modified as suggested for the second one. 4. No changes. Everyone has different targets. 5.1 Modified as suggested; (the format and font are checked again) 5.2 Good idea; Modified as suggested; 5.3 Translate the English references into Chinese would be better.

Table 5.10. Suggestions in the second-round content validity testing of the material

Code	Suggestions	Changes made
CN01 (Nurse)	1. About Chinese translation of “adolescents with type 1 diabetes” in the whole material can be changed into “type 1 diabetes”. 2. (3.2-page 21) • Once opened, insulin should be put in the house (< 30℃) can be changed into “< 25℃”; • Unused insulin should be in the refrigerator (4-8℃) can be changed into “2-8℃” 3. (3.5-page 30) • HbA1c can be only tested in the hospital. • For adolescents with type 1 diabetes, a target of HbA1c <7.5% is recommended to be optimal. • (3.5-page 31) There is a single-choice question about HbA1c target in the quiz. 4. (4.1-page 37) “The exact reason of low blood sugar cannot be known” sounds negative. 5. (4.3-page 43) If the complications will come to me sooner or later, it is all in vain for me to control my blood sugar, which is not easy. 6. (4.5-page 48) • At that time, it was hard to know exactly how much our blood sugar was. Urine testing was the only way to know blood sugar vaguely by observing the change of colors on the strips. • “Doing exercise of any kind really been affected due to diabetes” sounds negative;	1. Modified as suggested. 2. Modified as suggested; The ISPAD 2018 was also checked; 3. Modified after checked; • “Now, you can buy a special mentor to test HbA1c at home; if it’s not available for you, you can also go to the hospital to have blood sample”. • The target of HbA1c <7.5% can be changed into “<7.0%” (ISPAD 2018); • The options were changed into “A. <7.0mmol/L, B.7.0-9mmol/L, C. >9mmol/L”; 4. Be deleted. 5. Modified; “it is all in vain” can be changed into “it seems like to be”; 6. Modified as suggested; • You can only test sugar in the urine at home; and you needed to go to the hospital to test blood sugar. • I always insist on exercise.
CE01 (Endocrinologist)	(2.1, 2.2, 2.3) About “people with type 1 diabetes cannot produce insulin at all”, it was shown that some people with type 1 diabetes can still produce limited peptide C and insulin.	Modified; “people with type 1 diabetes nearly can’t produce insulin”

Code	Suggestions	Changes made
CE02 (Endocrinologist)	1. (2.1-page 5) "Type 1 diabetes has no relationship with the candy you eat." Can be changed into "The cause of type 1 diabetes has no …."; 2. (2.3-page 11) If your blood sugar before breakfast is more than 7.0 mmol/L, or blood sugar at any times is more than 11.1mmol/L, you could be diagnosed with diabetes. "blood sugar before breakfast" is not fasting blood sugar; 3. (3.2-page 20) It's normal that you may inject different kinds or amounts of insulin from others. You need to follow the treatment regimen your doctors make for you. 4. (4.1-page 36) When blood sugar is less than 3.9 mmol/L, you may have feelings, such as feel hungry, high heartbeat, sweating and shakiness. "Weakness" can be added in the typical symptoms of low blood sugar.	1. Modified as suggested; 2. Modified as suggested; "If your fasting blood sugar (without eating food for 10 hours and drinking for 8 hours) is more than7.0 mmol/L…" 3. Modified as follows: • You need to follow your own treatment regimen. Of course, your doctor would also adjust your treatment regimen according to your blood sugar controlling. And sometimes, you also need to adjust by yourself according to the food you eat, exercise you do, blood sugar levels and your doctors' suggestions. 4. Modified as suggested;
CD01 (Dietician)	1. (3.1-page 17) "Health food refers to the food low in fat, …." "low in sodium" can be added. 2. (3.2-page 21) About "high-intensity exercise has a beneficial effect on heart of people with diabetes." Is it evidential? If not, suggest to delete it. 3. About CGM (continuous glucose monitor), it can be changed into "continuous blood sugar monitor"; 4. (3.6-page 33) About "If you have no appetite, and your blood sugar is falling down 10 mmol/L, sugar-containing fluid need to be considered", is "blood sugar is falling down 10 mmol/L" evidential, if not, suggest to be deleted.	1. Modified as suggested; 2. Checked the guideline about exercise again; Modified as "it is more effective in improving heart fitness among people with diabetes" 3. No changes. CGM is not about blood sugar, rather than sugar in our body fluid. 4. No change. It was mentioned in ISPAD 2014 and ISPAD 2018 (sick day management).
CP01 (Psychologist)	Some format suggestions: • The "quiz" part can be highlighted like "Tips" by using a different colour. • The "frequently asked question" part can be highlighted or differentiated by using borders.	Modified as suggested;

5.4.4. Impact on the next stage

After readability and content validity testing, the T1DM educational material was tested to be understandable for adolescents at the age of 10-19 years, and scientific and consistent with the purpose of improving adolescents' diabetes knowledge, self-efficacy and adherence. Furthermore, the finalised type 1 diabetes educational material would be uploaded on the webpages for adolescents to study after the webpages were developed.

CHAPTER 6 SELECTION AND VALIDITY TESTING OF SCALES

Outcomes in clinical research refer to variables that are monitored during a study to document the impact of a given intervention or exposure on the health of a given population (Ferreira and Patino, 2017). Selecting appropriate outcomes is essential in designing a valid clinical study. The usefulness of a study as a contribution to clinical knowledge is based on selecting suitable outcomes for its purpose (Coster, 2013).

The ultimate end purpose of this study after a feasibility testing is to improve adolescents' diabetes knowledge, self-efficacy and adherence through the web-based T1DM educational material, and to assess usability of the webpages. Therefore, outcome measures of this study consist of diabetes knowledge, self-efficacy, adherence and webpage usability. Scales or questionnaires have been one of the most widely used ways to collect data in nursing research (Boynton and Greenhalgh, 2004). This chapter will focus on selection and validity testing of scales at four stages.

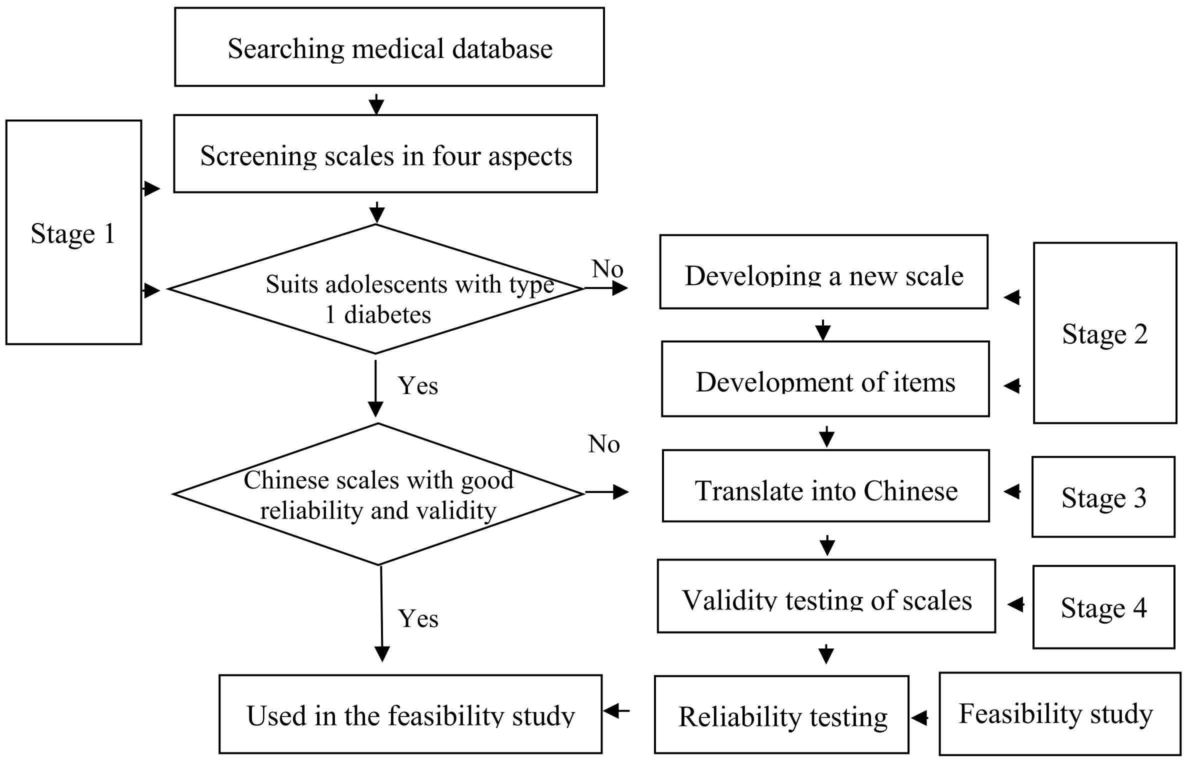


Fig 6.1. Flow chart of selection and validity testing of scales

6.1. Stage 1 (6/2018-2/2019): Selection of scales

6.1.1. Basic introduction

To save time and resources, a previously validated and published scale is the priority for researchers, and the findings can be also compared with findings from other studies. However, a valid and reliable scale developed in a different country or culture context may be not a valid and reliable measure (Boynton and Greenhalgh, 2004). Therefore, previous reliable and valid scales in Chinese or adapted into Chinese will be the top priority at this stage. Reliable and valid scales in English will be selected if there are no reliable and valid Chinese scales available as shown in Figure 6.1.

6.1.2. Steps taken at this stage

Step 1 (6/2018-12/2018): Search databases and screen articles

Cochrane library, Pubmed, Embase and Google scholar, and Chinese databases CNKI and Wanfang were searched about scales' development and psychometric testing in diabetes knowledge, self-efficacy, adherence and webpage usability. The key words included: "type 1 diabetes"; "child or kid or adolescent or youth or teen*"; "scale or questionnaire or instrument"; "diabetes knowledge"; "self-efficacy"; "adherence"; and "usability".

Several requirements were summarised to screen appropriate scales:

- Scales were developed to test diabetes knowledge, self-efficacy, adherence and webpages utility;
- Scales were specifically developed for children or adolescents with T1DM, and the items should be easy to understand;
- Without items which are not suitable for adolescents;

- Being reliable and valid;
- Regarding language; Chinese scales or scales which have been adapted into Chinese were the top priority; if not, scales in English were selected. Reviews and individual articles were screened to find as many scales as possible.

Step 2 (8/2018-2/2019): Comparison between scales regarding the four aspects of outcomes

Four data extraction forms were used to compare the scales testing the four aspects of outcomes, which also included reasons to exclude scales in this study.

(1) Comparison between scales regarding diabetes knowledge:

Ten scales about diabetes knowledge were found in existing articles, including the Mercy What I Know About Diabetes (M-WIKAD), the PedCarbQuiz (PCQ) scale, the Nutrition Knowledge Survey (NKS), the Spoken language in low-literacy patients with Diabetes Scale (SKILLD), the Diabetes Knowledge Scale (DKN), the Diabetes Knowledge Questionnaire (DKQ), the Diabetes Knowledge Test (DKT), the revised diabetes knowledge scale (RDKS)/simplified diabetes knowledge scale (SDKS), the Revised Diabetes Knowledge Test (RDKT2). No validated Chinese scales were found to be appropriate to measure diabetes knowledge in adolescents with T1DM.

The M-WIKAD scale with 19 items was developed for adolescents (12-18 years) with T1DM in 2019. This scale was excluded because unacceptable construct validity was reported in exploratory factor analysis, which needed to be tested further (Tsai et al., 2019). Although the PCQ and NKS scales were developed for adolescents with T1DM, the two scales were also excluded because only diet or insulin was tested, rather than comprehensive diabetes management (Koontz et al., 2010, Rovner et al., 2012). Another seven scales were developed for adults with type 2 diabetes or both type 1 and type 2 diabetes, which were excluded because involvement of some items made them difficult to understand by younger adolescents. Therefore, no scale about diabetes knowledge was found to be appropriate for this study. The form with comparison of the ten diabetes knowledge scales is shown in Table 6.1.

Table 6.1. Comparison between ten scales measuring diabetes knowledge

Scales	Items	Subjects	Other characteristics	Reasons to be excluded
Mercy What I Know About Diabetes (M-WIKAD)	19	Adolescents with T1DM	-Developed by Tsai in 2019;	Psychometrics need to be tested further
PedCarbQuiz (PCQ) scale	78	Adolescents with T1DM	- Developed by Koontz in 2010; - Reliable and Valid;	Only about carbohydrate and insulin-dosing
Nutrition Knowledge Survey (NKS)	23	Adolescents with T1DM	- Developed by Rovner in 2012; - Psychometrics need to be tested further;	Only about diet
SKILLD (Spoken language in low-literacy patients with Diabetes Scale)	10	Adult with T2DM	- Developed by Rothman in 2005; - 10 opened questions; - For T2DM and poor literacy; - Reliable and valid;	Just for people with T2DM
DKN (Diabetes Knowledge Scale)	15	Adult with T2DM	- Developed by Dunn in 1984; - 15 items (3 multi-choice questions); - Reliable and valid; - Translated by He in 2007 into Chinese/T2DM;	Just for people with T2DM
DKQ (Diabetes Knowledge Questionnaire)	15	Adult with T1DM and T2DM	- Developed by Villagomez in 1989/60 items; - Adapted by Garcia in 2001/24items/Spanish and English/for T2DM/reliable and valid; - Adapted by Eigenmann in 2011/15 item (6 multi-choice questions)/for T1DM and T2DM/reliable and valid;	Including 6 multi-choice questions, which is more difficult for younger adolescents

Scales	Items	Subjects	Other characteristics	Reasons to be excluded
DKT (Diabetes Knowledge Test)/ RDKT2 (Revised Diabetes Knowledge Test)	23	Adult with T1DM and T2DM	- DKT was developed by Fitzgerald in 1998; 23 items/14-item general diabetes and 9-item insulin usage; Reliable and valid; - Adapted by Fitzgerald in 2016 with miner change or grammar improving; reliable and valid;	The content is much difficult than younger adolescents can understand
RDKS (revised diabetes knowledge scale)/SDKS (simplified diabetes knowledge scale)	20/19	Adult with T1DM and T2DM	- Adapted by Collin in 2010 from DKT; - RDKS: 20items/True-false version; - SDKS: 19 items/multiple-choice responses; - Reliable and Valid;	True-false or multiple-choice responses, which are too simple or too difficult to finish

(2) Comparison between scales regarding self-efficacy in diabetes management:

Eleven scales about self-efficacy in English were found as shown in Table 6.2, and there were no validated Chinese scales to test self-efficacy in adolescents with T1DM. Seven scales in English were developed for adults with diabetes and excluded, including the Confidence in Diabetes Self-Care (CIDS) scale, the Diabetes Self-Efficacy Questionnaire (DSEQ), the Diabetes Management Self-Efficacy Scale (DMSES), the Diabetes Empowerment Scale (DES), the Adopted Insulin Management Diabetes Self-Efficacy Scale (IMDSES), the Diabetes Self-Efficacy Scale (DSES), the Perceived diabetes self-management scale (PDSMS). The Self-Efficacy in Diabetes Education (SEDE) was developed specifically for school nurse and was also excluded. Among the remaining three scales, including the Self-Efficacy for Diabetes Scale (SED), Diabetes-Specific Self-Efficacy scale (DSSE), and the Self-Efficacy in Diabetes Management (SEDM), the SEDM scale with 10 items was selected to be tested further in this study, which should be easier for younger adolescents to understand.

Table 6.2. Comparison between 11 scales measuring self-efficacy

Scales	Characteristics	Reasons to exclude
the self-efficacy in diabetes management (SEDM)	- Developed by Iannotti in 2006 for adolescents (10-16 years) with T1DM; - Based on Bandur's self-efficacy and Health Belief Model; - Be translated into Danish; 10items/2 sub-scales; - Reliable and Valid;	
The Confidence in Diabetes Self-Care (CIDS) scale	- Developed by Van der ven in 2003/Dutch and U.S. version; - 5-point Likert scale/20items/for adults (>18years) with T1DM; - Reliable and valid;	For adults with T1DM
Diabetes Self-Efficacy Questionnaire (DSEQ)	- Developed by Robin in 2004; - 6-point Likert scale/6 sub-scales; - For adults (18-90 years) with T2DM; - Reliable and valid;	For adults (18-90 years) with T2DM
Diabetes Management Self-Efficacy Scale (DMSES)	- Developed by Biji in 1999/20-items/for adults with T2DM; - Adopted by Sturt in 2009/15-items/for adults with T2DM; - Adapted in English "DMSES UK" by Sturt in 2010/for T2DM/15items; - Adapted in Australia; - Adapted in Chinese version (Taiwan, C-DMSES) by Wu in 2006/for adults (>30years) with T2DM; - Be translated into Chinese (Mainland) in 2016/20 items/for adults with T2DM/11 point/20-items/4 sub-scales; Reliable and valid;	For adults withT2DM
Diabetes Empowerment Scale (DES)	- Developed by Anderson in 2000/28-item DES/3 sub-scales/for adults (50.4±15.8years) with type 1 (25%) and type 2 diabetes/reliable and valid; - An 8-items DES-SF (in 2013); - Be translated into Chinese for type 2 diabetes (C-DES-20);	For adults with T1DM and T2DM
Adopted Insulin Management Diabetes Self-Efficacy Scale (IMDSES)	- IMDSES was developed by Hurley in 1990 in USA/for adults with T1DM/26-items/6-points Likerts/for individual using insulin; - Adapted by Gastal in 2007 in Brazil (Portuguese)/4-point Likert scale/20-items/for adults (33.9±14.97 years) with T1DM/reliable and valid;	For adults with T1DM

Scales	Characteristics	Reasons to exclude
Diabetes Self-Efficacy Scale (DSES)	- Developed by Hurley in 1992 in USA for adults with T1DM; - Adjusted by Ritter 2016 (DSES-S) in Spanish; 8items/10-points Likert scale/2 subscales/for adults with T2DM/reliable and valid; - Translated and adapted by Wang in Taiwan/26 items/non-insulin dependent; - Test by Wan in China in 2009/for T2DM;	For adults with T2DM
Perceived diabetes self-management scale (PDSMS)	- Developed by Wallston in 2007; - 8items /for adults (54.2±12.95 years) with type 1 diabetes/5-point Likert/Reliable and valid;	For adults with T1DM
Self-efficacy in diabetes education (SEDE)	- Developed by Fisher in 2006/11items/5-point Likert; - Design for school nurse to measure their perceived confidence level to perform diabetes care and education;	For school nurse
The Self-Efficacy for Diabetes Scale (SED)	- Developed by Grossman in 1987; - Based on Bandur's self-efficacy; - three sub-scales: diabetes-specific self-efficacy (SED-D), medical self-efficacy (SED-M), and general self-efficacy (SED-G); - For 10-16 years with T1DM in USA/35items; - Reliable and valid/measured psychometric property again by Allen in 2017;	Too long for younger adolescents
Diabetes-specific self-efficacy scale (DSSE)	- Developed by Littlefield in 1991; - For 13-18years with T1DM/7-items/9-point: A+=9, F=1; - Reliable and valid;	Content only about practical aspects, no emotional aspects

(3) Comparison between scales regarding adherence in diabetes management:

No validated Chinese scales were appropriate to measure adherence in adolescents with T1DM. Nine English scales were found to test adherence in diabetes management as presented in Table 6.3. The Diabetes Medication Adherence Scale (DMAS), the Iraqi Anti-Diabetic Medication Adherence Scale (IADMAS) and the Morisky Medication Adherence Scale (MMAS) were not specifically developed for people with DM, therefore were excluded. The Perceived Dietary Adherence Questionnaire (PDAQ) was only developed to measure dietary management among people with DM, which was also excluded. Another three scales, including the Adherence in Diabetes Questionnaire (ADQ), the Self-reported version of the Diabetes Self-Management Profile (DSMP) and the Diabetes Management Questionnaire (DMQ), were excluded because of limited psychometric properties. The Diabetes Self-Management Questionnaire (DSMQ) was excluded because it was only developed to test insulin regimens. Therefore, the Self-Care Inventory (SCI) with 14 items was selected because it was also developed for adolescents to test their adherence in diabetes management.

Table 6.3. Comparison among nine scales measuring adherence

Scales	Characteristics	Reasons to exclude
Self-Care Inventory (SCI)	- ACI (Self-Care Inventory): developed by La Greca for adolescents and adults (10-22 years) with T1DM and T2DM/14-items; - ACI-R: adapted by Weinger in 2005/5-point Likert scale/15-items for adults (>18years) with T1DM and T2DM; reliable and valid;	
Adherence in Diabetes Questionnaire (ADQ)	- Developed by Kristensen in 2012; - Developed for children and adolescents (2-17 years) and caregivers; - Two versions, ADQ-Conventional treatment (ADQ-C; 19 items) and ADQ-Insulin pump (ADQ-I; 17items); 5-point Likert scale; - Have a good internal consistency and concurrent validity;	Test-retest reliability and its sensitivity to changes were not tested;
Self-reported version of the Diabetes Self-Management Profile (DSMP)	- DSMP was developed by Harris in 2000 for adolescents (6-15 years) with T1DM with 23 items; It was tested to be reliable and valid; DSMP was a semi-structured interview-based scale; - Adapted by Wysocki in 2012 into a 24-item self-reported scale, DSMP-self-reported questionnaire (DSMP-SR); reliability and validity were tested;	Stability was not tested;
Diabetes Self-Management Questionnaire (DSMQ)	- It was adapted from the DSMP scale by Markowitz in 2011; - It is a brief, 9-item self-report questionnaire for young people (≥ 9 years); - Acceptable psychometric properties and construct validity;	All the items were only about insulin regimens;

Scales	Characteristics	Reasons to exclude
Diabetes Management Questionnaire (DMQ)	- It was developed by Mehta in 2015 for children aged 8-18 years with T1DM and their parents; - It is a 20-item and five-point Likert scale; - Internal consistency, test-retest reliability, predictive and convergent validity were tested to be acceptable;	For those (<13 years), it didn't have adequate psychometric properties;
Diabetes Medication Adherence Scale (DMAS)	- It was developed by Ayoub in 2012 for adults with T2DM to test adherence of oral anti-diabetic medication/with 7 items; - It had a good internal consistency and criterion-related validity;	Not specifically for people with diabetes;
Iraqi Anti-Diabetic Medication Adherence Scale (IADMAS)	- It was adapted from other scales, such as Medication Adherence Questionnaire (MAQ), Measurement of Adherence to the Treatment, Medication Compliance Questionnaire in 2019 by Mikhael; - It was a reliable and valid scale for assessing anti-diabetic medication adherence among Iraqi patients;	Not specifically for people with diabetes;
Morisky Medication Adherence Scale (MMAS)	- In 1986, Dr. Morisky developed the MMAS scale with 4 items; the specificity was low; - In 2008, an 8-item modified scale was developed with good sensitivity and specificity; then it became popular and commonly used;	Not specifically for people with diabetes;
Perceived Dietary Adherence Questionnaire (PDAQ)	- It was adapted from the Summary of Diabetes Self-care Activities measure and another two Nutrition Therapy recommendations in Canada by Asaad in 2015; - Developed for adults with T2DM with 7 items; - It was tested to be a valid and reliable scale;	Only about dietary management;

(4) Comparison between scales regarding webpage usability:

There were no validated and appropriate Chinese scales testing webpage usability in people with diabetes. Twelve scales about system or webpage usability were found in English, including the System Usability Scale (SUS), the Usefulness, Satisfaction, and Ease of use (USE questionnaire), the Website Analysis and Measurement Inventory (WAMMI), the Software Usability Measurement Inventory (SUMI), the Purdue Usability Testing Questionnaire (PUTQ), the Nielsen's Attributes of Usability (NAU), the Perceived Usefulness and Ease of Use (PUEU), the After Scenario Questionnaire (ASQ), the Post-Study System Usability Questionnaire (PSSUQ), the Computer System

Usability Questionnaire (CSUQ), the Usability Metric for User Experience (UMUE), and the Questionnaire for User Interface Satisfaction (QUIS). Finally, the System Usability Scale (SUS) with 10 items was selected to assess the webpages developed in this study. The 12 scales about system usability are presented in Table 6.4.

Table 6.4. Comparison between the 12 scales measuring webpage usability

Scales	Characteristics	Reasons to be excluded
SUS (System Usability Scale)	- Developed by Brooke in 1996/10 items/5-point Likert/no reliability and validity test (system); - Adapted by Bangor in 2008/10 items/5-point Likert/reliable and valid (product); - Can produce reliable results when sample size is more than 12;	
USE questionnaire (Usefulness, Satisfaction, and Ease of use)	- Developed by Lund in 2001; - 30 items/Likert 7 points/4 sub-scale; - No reliability and validity test;	No information about reliability and validity test
WAMMI (website analysis and measurement inventory)	- Developed by Human Factors Research Group in 1999; - 20 items/no access to use (needs to be paid);	Need to be paid
SUMI (the software usability measurement inventory)	- Developed by Kirukowski in 1993; - 50 items/no access to use (needs to be paid);	Need to be paid/50items
PUTQ (Purdue usability testing questionnaire)	- Developed by Lin in 1997; - 100items/8-sub-scale; - Reliable and valid;	Too long for young adolescents/100 items
NAU (Nielsen's attributes of usability)	- Developed by Nielsen in 1993; - 5 attributes (aspects);	No specific questions
PUEU (Perceived usefulness and ease of use)	- Developed by Davis in 1989; - 12 items/2 sub-scale: perceived usefulness (the degree of the system to enhance job performance) and ease of use; - Reliable and valid;	The content is not suitable (for job performance)
ASQ (After scenario questionnaire)	- Developed by Lewis (IBM) in 1993; - 3 questions/7-point Likert; - Acceptable reliability and validity;	Contents are limited (3 items)

Scales	Characteristics	Reasons to be excluded
SUS (System Usability Scale)	- Developed by Brooke in 1996/10 items/5-point Likert/no reliability and validity test (system); - Adapted by Bangor in 2008/10 items/5-point Likert/reliable and valid (product); - Can produce reliable results when sample size is more than 12;	
USE questionnaire (Usefulness, Satisfaction, and Ease of use)	- Developed by Lund in 2001; - 30 items/Likert 7 points/4 sub-scale; - No reliability and validity test;	No information about reliability and validity test
WAMMI (website analysis and measurement inventory)	- Developed by Human Factors Research Group in 1999; - 20 items/no access to use (needs to be paid);	Need to be paid
SUMI (the software usability measurement inventory)	- Developed by Kirukowski in 1993; - 50 items/no access to use (needs to be paid);	Need to be paid/50items
PSSUQ (The Post-Study System Usability Questionnaire)	- Developed by IBM in 1991; - 19items/4 sub-scale; - reliable and valid;	The content is not suitable (item3.4.5.8.14)
CSUQ (Computer System Usability Questionnaire)	- Developed by IBM in 1992; - 19items/7-point Likert; - Reliable and valid;	The content (similar to PSSUQ: item 3,4,5,8,14)
UMUE (the Usability Metric for User Experience)	- Developed by Finstad in 2010; - 4 items (4th: spent much time on correcting things with this system)/7-point Likert; - Reliable and valid;	4th item is not suitable
QUIS (Questionnaire for User Interface Satisfaction)	- Developed by Chin 1988; - 27items/10 points/5 sub-scale; - Reliable and valid;	7 itms are not suitable (no order NO.)

6.1.3. Results

Three scales were selected to be tested further in this study, including the Self-efficacy in Diabetes Management (SEDM) to measure self-efficacy, the Self-Care Inventory scale (SCI) to test adherence and the System Usability Scale (SUS) to evaluate webpage usability.

6.1.4. Impact on next stage

At this stage, three scales regarding self-efficacy, adherence and webpage usability were selected. However, existing scales about diabetes knowledge were not appropriate for this study. Therefore, a new type 1 diabetes knowledge scale was developed, which will be mentioned at the next stage.

6.2. Stage 2(7/2018-2/2019): Development of the Type 1 Diabetes Knowledge scale

6.2.1. Basic introduction

As mentioned, there was no diabetes knowledge scale found to be suitable for this study. Therefore, a scale specifically for adolescents with T1DM at the age of 10-19 years needed to be developed in this study to test their knowledge about self-care issues. The most practical and straightforward way to develop a scale was reported as gleaning information from a literature review to develop key questions (Timmins, 2015), which was how items emerged in this new type 1 diabetes knowledge scale. At this stage, the process to form preliminary items of the new T1DM knowledge scale will be presented in three steps.

6.2.2. Steps taken at this stage

Step 1 (7/2018-9/2018): Literature review about diabetes knowledge

Pubmed, EBSCO, Cochrane, Web of Science, and Chinese databases CNKI and Wanfang were systematically searched to find the articles about development and psychometric testing of diabetes knowledge. Although there was not one appropriate for 10-19-year adolescents with T1DM, the existing scales were analysed to provide the content structure for the new-developed scale (Timmins, 2015).

Step 2 (8/2018-2/2019): Analysis of content structures of the existing scales

The content of the existing diabetes knowledge scales was analysed to check whether any theory framework could be summarised to structure the new scale. In addition to the PCQ and NKS scales testing diet or insulin, the main content structures of another eight scales consisted of diabetes management (insulin, blood sugar testing, diet, exercise, diabetes management in sick days) and diabetes complications (acute and chronic complications), which are summarised in Table 6.5.

Table 6.5. Content structure of existing scales about diabetes knowledge

Scales	Content structure
M-WIKAD (Mercy What I Know About Diabetes)	• Advanced problem solving; • Hypoglycemia prevention and management; • Taking medication/insulin administration; • Daily management; • Healthy active living;
SKILLD (Spoken language in low-literacy patients with Diabetes Scale)	• Normal fasting blood sugar (1 item); normal HbA1c (1 item); • Exercise (1 item); • Signs of high blood sugar (1 item); signs and treatment of low blood sugar (2 items); • Frequency and importance of feet check (2 items); • Eye screen (1 item); • what are long-term complications (1 item);
DKN (Diabetes Knowledge Scale)	• Uncontrolled diabetes (1 item); • Relationships between diabetes controlling and complications (1 item); • Normal blood sugar (1 item); Urines sugar testing (1 item); • Food (2 item), eating (2 item), carb calculation (2 item); • Ketones (1 item); • Long-term complications (1 item); • Insulin management in sick days (1 item); • Low blood sugar reaction (2 item);

DKQ (Diabetes Knowledge Questionnaire)	• Normal blood glucose levels (fasting/HbA1c-2 items); • Can diabetes be cured (1 item); • Diet (1 item); • Exercise (2 items); • Self-monitoring of blood glucose (1 item) • Low blood sugar reaction (1 item); • Sick-days management (1 item); Sick-days for people with T1DM only (1 item); • Long-term complications (1 item); • Foot check (1 item); • Annual check-ups (1 item); • Support services of National Diabetes Services Scheme (1 item) • Medication for type 2 diabetes (1 item);
DKT (Diabetes Knowledge Test)/RDKT2 (Revised Diabetes Knowledge Test)	• Diet, food and diabetes (5 item); • Blood sugar testing (2 item); • Excise (1 item); • Relationship between infection and blood sugar (1 item); • Sick day management (1 item); • Feet check (1 item); • Long term complications (3 item); • Acute complication, including low blood sugar (1 item), DKA (1 item); • Insulin use (7 item);
RDKS (revised diabetes knowledge scale)/SDKS (simplified diabetes knowledge scale)	• Diabetes diet (7 items) • Exercise (1 items) • Blood glucose testing/HbA1c (3 items) • Insulin (0/1 items) • High blood pressure (1 items) • Acute complication, including low blood glucose (1 items) • Long-term complication, including numbness and tingling (1 items) • Infection (1 items) • Feet check (1 items) • Associated problems (1 items) • Sick day management (1 items) • Clinic appointments (1 items)

Step 3 (8/2018-2/2019): Formation of preliminary items in the new-developed scale

Preliminary items for the new type 1 diabetes knowledge scale were generated based on the two main content structures of the existing scales, including different components of diabetes management, and signs and prevention of diabetes complications. Another three aspects, including definition, symptoms and diabetes check-up, were screened from the existing scales and involved in the newly developed diabetes knowledge scale, which would be suitable for adolescents (Eigenmann et al., 2011; Garcia et al., 2001).

As shown in Figure 6.2, a 10-item Type 1 Diabetes Knowledge (T1DK) scale was preliminarily developed in five domains, including: definition of type 1 diabetes (2 items); typical symptoms of type 1 diabetes (1 item); diabetes management (diet, exercise, blood sugar testing, HbA1c, management in sick days; 5 items); complications (low blood sugar, 1 items); and regular check-ups (1 item).

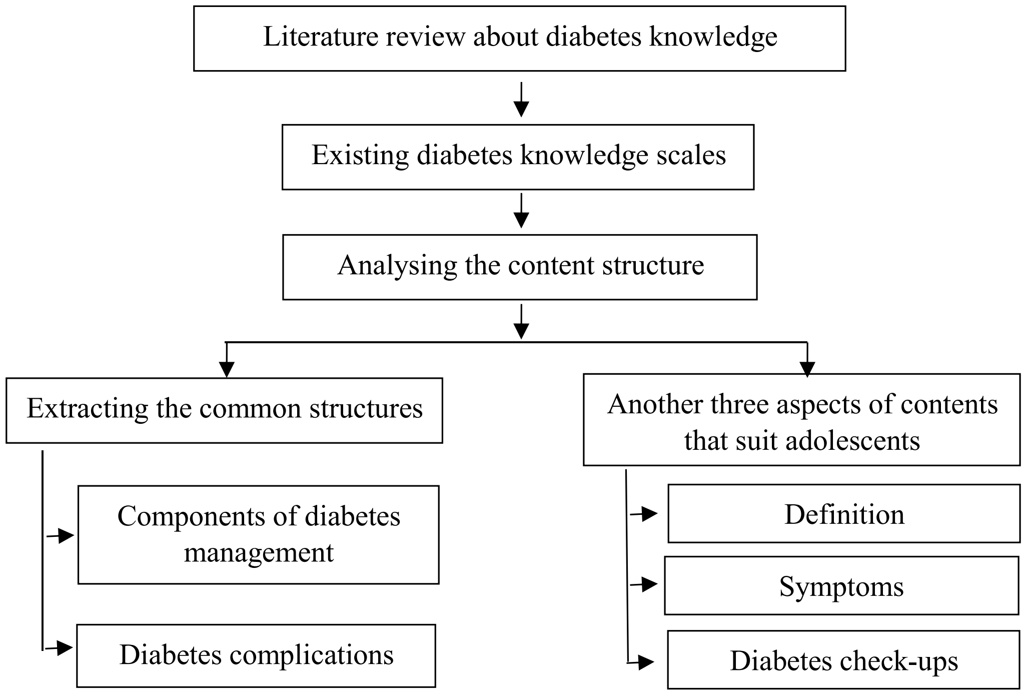


Fig 6.2. Identification of the 5 domains for the Type 1 diabetes knowledge scale

6.2.3. Results

The preliminary Type 1 Diabetes Knowledge (T1DK) scale is a 10-item scale about type 1 diabetes knowledge in five domains, which is a single-choice scale. Every item has three options and only one of them should be correct. The 10-item preliminary scale with three options in each item is presented in Table 6.6. The correct answers are also marked with underlining.

Table 6.6. The preliminary type 1 diabetes knowledge scale

Domains	Items
Definition	1. What is type 1 diabetes (T1DM)? A. The body cannot produce sugar and lacks energy as a result. B. The body cannot produce insulin at all. C. The body cannot use insulin properly.
	2. T1DM is a condition that A. Can be cured with tablets or insulin. B. Can be cured by adapting a healthy lifestyle. C. Currently cannot be cured.
Symptom	3. Which of these is not a symptom of T1DM? A. Obesity B. Always thirsty C. Always hungry
Diabetes management	4. HbA1c reflects the blood sugar levels A. At the day when I have blood test B. In the past week C. In the past 6-12 weeks
	5. Which of the following statements about T1DM and diet is true? A. People with T1DM can eat sugar free diet without limitation. B. People with T1DM cannot eat any fruit at all. C. A diet which is low in fat, high in fibre and low in added sugar is recommended for everyone with T1DM
	6. How often should people with T1DM like you who have no serious complication do exercise? 3-5 days a week for at least 30 minutes B. Once a week for at least one hour C. Once a month for 2 hours
	7. Why are people with T1DM like you advised to test the blood sugar? A. To alert us the change in blood sugar levels B. To help provide evidence for exercise, treating lo or high blood sugar, and sick-day management C. Both of them
	8. What should people with T1DM like you do if you become ill (e.g. cold, infection) A. Check blood sugar level more frequently (every 2 to 4 hours) B. Stop taking insulin C. Try to do as much exercise as possible to lower blood sugar levels
Regular check-ups	9. Why should people with T1DM like you have an annual check-up: A. Annual check-up can avoid diabetes complications B. Annual check-up can help doctors discover long-term complications in time C. Annual check-up can lower blood sugar
Complications	10. If people with T1DM like you have a low blood sugar, you should: A. Immediately take some insulin B. Have a rest until she/he feels better C. Immediately have some sugar food or drink (e.g. fruit juice, honey)

6.2.4. Impacts on next stage

At this stage, a preliminary Type 1 Diabetes Knowledge (T1DK) scale was developed with 10 items based on content structures of existing scales. However, psychometric properties should be tested to demonstrate if the new scale is reliable and valid to be used in a certain group of population (Rattray, 2005). In addition, the three scales which were selected in the first stage had not been translated into Chinese and validated in adolescents with T1DM in China. Therefore, at next two stages, readability and content validity will be conducted to test whether the four scales can be clearly understood by adolescents, and whether the contents are scientific.

6.3. Stage 3 (2/2019-4/2019): Translation, adaption and readability testing of scales

6.3.1. Basic introduction

The three scales selected about self-efficacy, adherence and webpages usability were developed in English, as well as the new-developed Type 1 Diabetes Knowledge (T1DK) scale. The four scales were not adapted and used among Chinese adolescents with T1DM. Therefore, before content validity testing, translation, cultural adaption and readability testing will be conducted at four steps.

6.3.2. Steps taken at this stage

Step 1 (2/2019-3/2019): Forward translation and transcultural adaption

The four scales were developed in English, which needed to be translated forward into Chinese. To keep the conceptually equivalent between the Chinese version (the target language) and English version (the original language), the translation process will focus on the cross-cultural and conceptual equivalence, rather than on linguistic equivalence. According to the WHO translation and adaption framework, the translator who conducted forward translation should be knowledgeable of the English-speaking culture but his/her mother tongue should be Chinese in this study. Therefore, the four scales were translated forward into Chinese by me who had been stayed in UK more than two years as a PhD student from China. The WHO translation guideline was followed during the translation process by using easy-understanding words.

About transcultural adaption, several specific challenges were found in the three scales.

- In the Self-efficacy in Diabetes Management (SEDM) scale, the idiomatic phrase "feel overwhelmed" in the item 8 "Manage your diabetes even when you feel overwhelmed" cannot be understood literally by Chinese person. After checking dictionary and consulting native-speakers, item 8 was translated into "Manage your diabetes even when you have too many things to do" in Chinese.

- In the Self-Care Inventory (SCI) scale, item 14 "Exercising strenuously" was a challenge, which was translated into "Exercising with great effort" in Chinese.

- In the System Usability Scale (SUS), item 2 "I found the system unnecessarily complex" did not conform to Chinese expression habits if it was translated literally, which was translated into "I found the system is too complex, which is not necessary" in Chinese.

Step 2 (3/2019-4/2019): Backward translation

According to the WHO translation and adaption framework, the four scales were translated backward into English by a colleague of mine who is a Registered Nurse with a Master's degree in China. Her major is not diabetes and she had no knowledge of the four scales in this study before backward translation. She had been an academic visitor in the UK for a year. The four Chinese scales were sent to her with the WHO translation guideline. Two weeks were given for her work.

Step 3 (4/2019): Comparison between versions

After backward translation was returned, the original English version and back translation version were compared. Only some words were backward translated differently, rather than incorrectly, which was thought to be acceptable. For example, option A of item 1 “the body cannot produce sugar and lacks energy as a result” is the original English version of the new-developed T1DK scale, which was backward translated into “the body cannot produce sugar, resulting in a lack of energy”. There were no changes made in the four scales after back translation.

Step 4 (4/2019): Readability testing

To check whether there were any words or sentences adolescents could not understand, readability of the four scales was tested among seven adolescents without diabetes at the age of 10-19 years in China. The same seven adolescents also had been invited to test the readability of the type 1 diabetes educational material in chapter 5. Only three medical terms in the Self-Care Inventory scale (SCI) were marked, which are presented in Table 6.7. The three medical terms may be not easy for adolescents without diabetes to understand but are necessary for adolescents with T1DM to know. In addition, examples were also provided in the brackets.

Table 6.7. The phrases hard to understand in the Self-Care Inventory scale

Order	Phrases	Changes made
1	Glucose testing	Glucose testing (such as blood sugar testing)
2	Glucose recording	Glucose recording (such as recording blood sugar values)
3	Ketone testing	Ketone testing (blood or urine sampling testing at home or in the hospital)

6.3.3. Results

At this stage, the four scales, including the Type 1 Diabetes scale (T1DK), the self-efficacy in diabetes management (SEDM), the Self-Care Inventory (SCI) and the System Usability Scale (SUS), were translated into Chinese, which were kept to be equivalent to the original English version and adjusted to suit Chinese expression habits. There were no changes after backward translation. However, three medical terms were illustrated further after readability testing in seven adolescents without diabetes.

6.3.4. Impact on next stage

After readability testing, the four scales still needed to be tested whether the contents were scientific and clinically correct in China, which was face and content validity testing at next stage.

6.4. Stage 4 (2/2019-6/2019): Face and content validity testing of the four scales

6.4.1. Basic introduction

In addition to readability testing among adolescents, face and content validity of the four scales need to be tested among experts, including the new developed T1DK scale. This aims to test the grammar, organisation and appropriateness, and test whether the items of the scales sample the complete range of the attribute under study (DeVon et al., 2007).

6.4.2. Steps taken at this stage

Step 1 (2/2019-3/2019): Face validity testing

Although face validity is a subjective assessment, it also provides insight into how potential users might interpret and respond the items of the scales. Experts or lay people can be invited to assess the grammar, syntax, appropriateness, organisation and confirmation of the logic (DeVon et al., 2007). In this study, two Chinese endocrinologists (CE01, CE02) were invited to test the face validity of the four scales. All the feedback was about the newly developed T1DK scale, which were divided into three categories with the solutions in Table 6.8.

Table 6.8. The problems mentioned during face validity testing of the SUS scale

Order	Problems mentioned	Solutions
1	Some words would be difficulty for younger adolescents: 1. The various functions in the system were **well integrated**. 2. **There was too much inconsistency** in this system. 3. I found the system very **cumbersome** to use.	1. Be changed into "well related to each other"; 2. Be changed into "there were some contents which do not match with each other"; 3. Be changed into "have too many functions, which lead to inconvenience to use"
2	The introduction of scales is difficult to understand for adolescents.	Added "Tips" part at the top of every scale as simple as possible;
3	Emoji may be better for younger adolescents to understand the options in Likert Scales.	Added Emoji in the "Tips" part;

In addition to some words, introductions of the four scales were suggested to be re-edited to be as simple and easy to understand as possible for adolescents. Experts suggested: "Tips" part can be added in each scale to help participants know what they needed to do in the scales as quickly as possible. In addition, three Likert scales were involved in this study, including the SEDM scale with options ranging from 1 (not sure at all) to 10 (completely sure), and the SCI and SUS scales which were 5-point Likert scales. To help participant understand differences between levels of measurement in the three Likert scales, emoji was designed by me and added in the "Tips" part as shown in Figure 6.3.

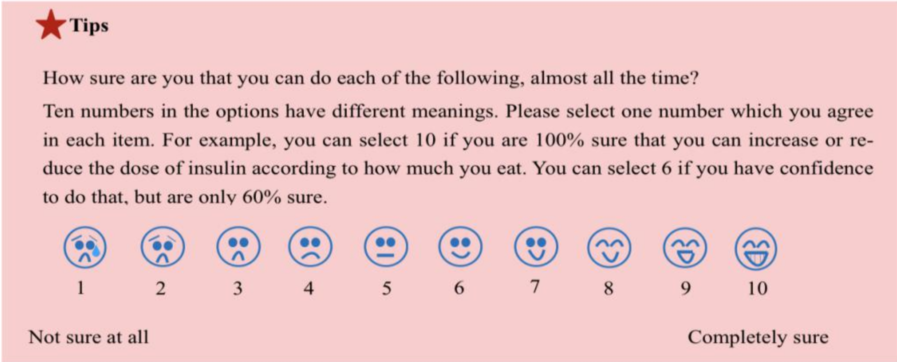


Fig 6.3. The "tip" part of the Self-Efficacy in Diabetes Management scale

Step 2 (4/2019-5/2019): Content validity testing of the three existing scales

Content validity of the three existing scales was tested among four experts in China, including two diabetes nurses (CN01, CN02) and two endocrinologists (CE01, CE02). They were invited to check whether the items of the three scales in Chinese were appropriate indicators of the construct. There were no changes mentioned in the Self-efficacy in Diabetes Management (SEDM), Self-Care Inventory scale (SCI) and System Usability Scale (SUS).

Step 3 (4/2019-6/2019): Content validity testing of the new-developed T1DK scale

The Type 1 Diabetes Knowledge (T1DK) scale was developed in this study. Ten Chinese experts were invited to review the potential scale items and assess whether the items were appropriate indicators of the construct. The ten Chinese experts included five endocrinologist (CE01-05) and five nurses (CN01-05) from the Affiliated Hospital of Southwest Medical University. The information is summarised in Table 6.9.

Table 6.9. Details of experts in content testing of the diabetes knowledge scale

Code	Profession	Education background	Work experiences (years) in diabetes
CE 01	Endocrinologist	Doctor degree	8
CE 02	Endocrinologist	Master degree	5
CE 03	Endocrinologist	Master degree	30+
CE 04	Endocrinologist	Master degree	6
CE 05	Endocrinologist	Master degree	10+
CN 01	Diabetes Nurse	Bachelor degree	30+
CN 02	Diabetes Nurse	Bachelor degree	30-
CN 03	Diabetes Nurse	Bachelor degree	7
CN 04	Diabetes Nurse	Master degree	1+
CN 05	Diabetes Nurse	Bachelor degree	9

An invitation letter, an assessment form and the T1DK scale in Chinese was given to the ten experts in China to assess the relevance of every item of the T1DK scale. If the item was relevant, they could tick "√" in the box of "relevant"; if not, they could tick "√" in the box of "irrelevant". If extra items needed to be added, they could mention this at the bottom of the assessment form. They could also comment on the document of the T1DK scale if they had any advices about words or phrases.

As a result, all ten experts gave the relevance ratings of items. Some suggestions about words and phrases were mentioned, and two items about insulin usage and DKA were suggested to be added by some experts, which will be presented in "Results" part.

6.4.3. Results

(1) Items relevance ratings on the original 10-item scale by 10 experts

- The content validity index for items (I-CVI) refers to the content validity of every individual item (Polit and Beck, 2006). In the T1DK scale, I-CVI = (1.00*8+0.90+0.80)/10 = 0.97.

- The content validity index for scales (S-CVI) can be used to test the content validity of the overall scale. S-CVI/UA (universal agreement) refers to the proportion of items given a rating of "relevant" by all the experts involved (Polit and Beck, 2006). In this scale, S-CVI/UA = 8/10 = 0.8.

- S-CVI/Ave refers to the average proportion of items rated "relevant" across the experts. In this scale, S-CVI/Ave = (1.00*7+0.90*3) = (1.00*8+0.90+0.80) = 0.97.

If I-CVI≥ 0.78, S-CVI/UA≥0.4 and S-CVI/Ave≥0.9, it is acceptable (Lynn, 1986, Polit and Beck, 2006). Therefore, content validity of the newly developed T1DK scale was acceptable. Table 6.10 presents item relevance marked by every expert.

Table 6.10. Items relevance ratings of the Type 1 Diabetes Knowledge scale

Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Expert 9	Expert 10	NO. in agreement	Item CVI
1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10	1.00
2	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10	1.00
3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10	1.00
4	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10	1.00
5	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10	1.00
6	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10	1.00
7	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10	1.00
8	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	9	0.90
9	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10	1.00
10	Y	Y	Y	Y	Y	N	Y	N	Y	Y	8	0.80
Proportion relevant	0.90	1.00	1.00	1.00	1.00	0.90	1.00	0.90	1.00	1.00	Mean I-CVI=0.97 S-CVI/UA=8/10=0.80 Mean expert proportion=0.97	
UA=Universal agreement, universally congruent ratings by the experts;												

(2) Specific suggestions from experts about expression problems of the T1DK scale

Table 6.11. Specific suggestions about the Type 1 Diabetes Knowledge scale

Item	Problems or suggestions	Way to resolve
1. What is type 1 diabetes (T1DM)? A. The body cannot produce sugar and lacks energy as a result. B. The body cannot produce insulin at all. C. The body cannot use insulin properly.	1. It was proved 1/3 patients with T1DM can produce insulin, although not much. 2. Peptide C was measured to be very low in type 1 diabetes patients' blood, which is carried out to find how much insulin our body is producing.	Be changed into "The body can nearly produce insulin";
3. Which of these is not a symptom of type 1 diabetes? A. Obesity B. Always thirsty C. Always hungry	1. Some patients with T1DM can also be obese even though most of them have a normal or decreased weight. 2. A suggestion: B: Feel thirsty, and drink plenty of water C: Feel hungry, and eat too much 3. A suggestion: "Which of these is not a typical symptom of type 1 diabetes onset? "	Be changed into "Which of these is not a typical symptom of type 1 diabetes?"
5. Which of the following statements about type 1 diabetes and diet is true? A. People with type 1 diabetes can eat sugar free diet without limitation. B. People with type 1 diabetes cannot eat any fruit at all. C. A diet which is low in fat, high in fibre, and low in added sugar suits for everyone with type 1 diabetes	Suggested to be change into: "low in added sugar" can be changed into "low in sugar"	Change as suggested;
6. How often should people with type 1 diabetes like you who have no serious complication do exercise? A. 3-5 days a week for at least 30 minutes B. Once a week for at least one hour C. Once a month for 2 hours	1. Problem: Diabetes complications include acute and chronic complications. How to assess if the complications are serious? 2. A suggestion: The question can be changed into: "How often should people with type 1 diabetes do exercise during stable stage?"	No change;

Item	Problems or suggestions	Way to resolve
7. Why are people with type 1 diabetes like you advised to test the blood sugar? A. To alert you the change in blood sugar levels B. To help you make right decision at some special time, such as exercising, treating low or high blood sugar C. Both of them	A suggestion: A. To alert you the change in blood sugar levels, and to keep blood sugar value as normal as possible (Premeal: 4-7 mmol/L, Postmeal: 5-10 mmol/L)	No change; too much detail;
8. What should people with type 1 diabetes like you do if you become ill (e.g. cold, infection) A. Check blood sugar level more frequently (every 2 to 4 hours) B. Stop taking insulin C. Try to do as much exercise as possible to lower blood sugar levels	Problem 1: It is hard to practice to test blood sugar every 2-4 hours. Problem 2: not too relevant; A suggestion: Or it can be changed into: "Why do you need to monitor blood sugar more frequently"	Problem1: Deleted "every 2 to 4 hours" Problem 2: No change; Item 7 mentioned the content about blood sugar test;
9. If people with type 1 diabetes like you have a low blood sugar (<3.9mmol/L), you should: A. Immediately take some insulin B. Have a rest until she/he feels better C. Immediately have some sugar food or drink (e.g. fruit juice, honey)	Suggestions from 2 experts: "If people with type 1 diabetes like you have feelings, such as hungry, sweating, and fast heartbeat, and blood sugar is less than 3.9 mmol/L, you should"	No change; too much detail;
10. Which of the following statement about diabetes checkups is FALSE? A. Keep checking feet daily for any changes like cuts, blisters. B. Regular diabetes check-up can lower blood sugar. C. Annual diabetes check-up can help your doctor spot the early signs of diabetes complications.	Problem 1: diabetes feet always happen to type 2 diabetes, however, rarely happen to 10-19-year adolescents with type 1 diabtes. (3 experts) Problem 2: unclear purpose and can be deleted;	It is changed into: A. Check-up of eyes, nerve, heart and kidney once a year in the hospital
Other suggestions: (1) Insulin injection is the only way to treat type 1 diabetes, which should be included in the scale. (4 experts) (2) Adolescents with type 1 diabetes always are hospitalised because of diabetic ketoacidosis (DKA), which should be included in the scale. (3 experts) (3) The target of blood sugar controlling should be mentioned in the scale; (4) Considering targeted age, can the items be described in more interesting ways?	Way to resolve: (1) Changed as suggestion; (2) Changed as suggestion; (3) No changed because everyone may have different targets. (4) No change this time; Good suggestion but hard to practice; It deserves to be considered.	

(3) Two items were added as suggested

Insulin injection was suggested to be added in the T1DK scale by four experts because insulin is still the only way to treat T1DM. Diabetic ketoacidosis (DKA) was mentioned to add by three experts because many adolescents with T1DM are hospitalised because of DKA. Therefore, another two items about insulin injection and DKA were added as showed in Table 6.12.

Table 6.12. The two added items in the Type 1 Diabetes Knowledge scale

Order	Added items
1	Which of the following statement about insulin storage and injection is FALSE? A. Before lunch you realised that you forgot to take your insulin at breakfast, you should check your blood sugar to decide how much insulin to take. <u>B</u>. Unused insulin should be stored in a freezer (<0℃), and after first usage insulin can be kept at room temperature (<25℃). C. Rotation of injection sites are important in different areas, such as abdomen, front and lateral thigh, and also important within the same area.
2	Which of the following statement about diabetic ketoacidosis (DKA) is FALSE? A. When you have the symptom of vomiting, deep sighing breath, breath smell like rotten apple, or even coma, you may be experiencing DKA. B. If you suspect yourself to have DKA, you need to test your blood sugar immediately, drink lots of water, or go to hospital if necessary. <u>C</u>. Maybe DKA can happen to people like you if you inject excess insulin and eat less food.

6.4.4. Impact on next stage

In this chapter, three appropriate scales in English were selected to test self-efficacy, adherence and usability of webpages, and the Type 1 Diabetes Knowledge scale was developed in this study. After translation and transcultural adaption, the readability, face and content validity were tested to assure that the scales can be understood by adolescents and contents of the scales were scientific and appropriate indicator of the construct in the scales. The reliability of the four scales will be tested in a feasibility study. The four scales in English and Chinese are presented in Appendix 11.

6.5. A summary of the selected or developed scales with validity testing in this study

In this chapter, there was no validated Chinese scales appropriate for adolescents with T1DM. Therefore, three validated scales in English were selected to test self-efficacy, adherence and webpage usability in this study, and a 12-item Type 1 Diabetes Knowledge scale was developed to measure diabetes knowledge in adolescents with T1DM. After translated, the four scales were assessed to be understandable with acceptable content validity as shown in Table 6.13.

Table 6.13. A summary of the four scales and validity testing in this study

Items	Type 1 diabetes knowledge scale (T1DK)	Self-efficacy in Diabetes Management (SEDM)	Self-Care Inventory scale (SCI)	System Usability Scale (SUS)
Measures/items	Diabetes knowledge (12 items)	Self-efficacy (10 items)	Adherence (14 items)	Webpage usability (10 items)
Target population	Developed in this study for adolescents with T1DM aged 10-19 years;	Developed for 10-16-year adolescents with T1DM;	Developed for 10-22-year adolescents with T1DM;	Developed for adults; however, no item does not suit adolescents.
Psychometric properties in English	Being not tested in English;	Reliable and valid (Iannotti, 2006) (Lindkvist,2017)	Reliable and valid (Lewin, 2009)	Reliable and valid (Bangor, 2008)
Translation and cultural adaption	Forward translation and cultural adaption were conducted by me, and backward translation was conducted by a colleague of mine who is familiar with English culture; Different versions were checked to ensure the consistency of the meanings;			
Readability testing	Seven adolescents without diabetes were recruited to test readability of the four scales; The four scales were assessed to be understandable;			
Face validity	Two Chinese endocrinologists were invited to test the face validity of the four scales to evaluate the grammar, appropriateness and organisation.			
Content validity	Five endocrinologist and five nurses scored the relevance of the scale;	Content validity of the three existing scales was tested among four experts in China, including two diabetes nurses and two endocrinologists;		
	The content validity of the four scales was acceptable;			

CHAPTER 7 DEVELOPMENT OF WEBPAGES

Webpage design and development played an essential role in this study because the Type 1 diabetes educational material needed to be uploaded on the webpages for participants to study. Design and development of the webpages were conducted by me, a Registered Nurse in China, and two engineers who had engaged in the webpage development for 6-9 years in China. According to the software development lifecycle (Borycki et al., 2011), the process of webpages design and development was divided into five stages as described in Figure 7.1.

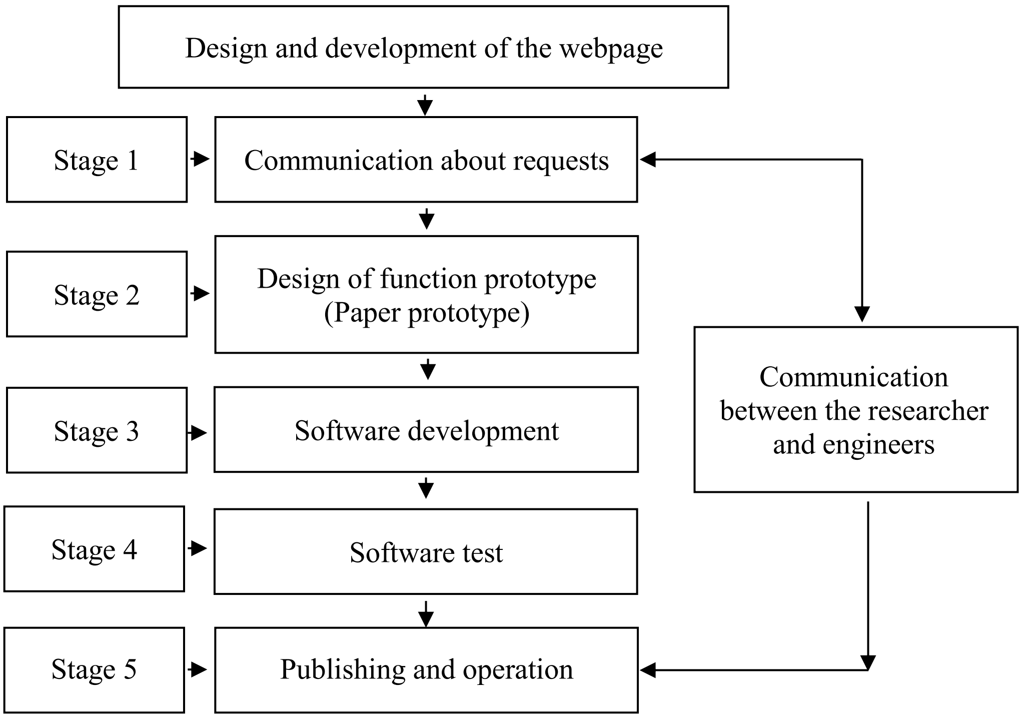


Fig 7.1. Flow chart of webpage design and development process

7.1. Stage 1 (6/2018-7/2018): Communication about requests

7.1.1. Basic introduction

I had no previous background or experience of webpage development before this study, and the two engineers also had no medical background. Communication between me and engineers was very important throughout the whole development process; this cannot be emphasised enough. WeChat® played an essential role in communication because I was studying in the UK as a PhD student and the two engineers were in China.

7.1.2. What was done at this stage and important questions addressed

Topics discussed between me and engineers at this stage included targeted audience, purpose of the webpages, how many webpages were needed and functions of each page, and whether the webpages needed to be linked to other webpages, maintenance, ownership, cost, deadline and a schedule. In this study, the webpages were not linked to other webpages because of technology and time limit. In addition, by consensus, the researcher takes ownership of the webpages.

In this study, considering the funding issue, webpage development was selected, rather than development of an app. Furthermore, another important issue required to be considered at this stage, that was, which kind of webpages would be required in this study, mobile webpages or personal computer (PC) webpages. If mobile webpages were developed, although the websites could be opened on the PC, the layout would be inadequate, and vice versa. Both mobile and computer could appropriately access the webpages only if the mobile and PC versions were developed, separately. In this study, we considered that adolescents aged 10-19 years would have more access to mobile phone in China, rather than a computer (CNNIC, 2019b). In addition, the budget and time were also limited for me. Therefore, the webpages were designed for mobile access only.

Mobile webpages are different from webpages on a personal computer in some aspects, such as a small screen size, only one page could be displayed at a time and navigation problem (Napoli and Obar, 2013). Personal computer is in landscape (widescreen) orientation and the mobile is always in portrait (vertical) orientation, which affects the design of webpages.

7.1.3. Impact on next stage

Proposed functions of the webpages were discussed to be explicit for both me and engineers. After communication, the webpages in this study were designed to consist of registration page, log-in page, homepage, type 1 diabetes educational pages and scale pages, which provided the foundation for the development at the next stage.

7.2. Stage 2 (8/2018-3/2019): Design of function prototype (a paper prototype)

7.2.1. Basic introduction

During communication about requests, the functions of each webpage were discussed and agreed. However, there was still a gap between request communication and webpage development. According to the research-based web design & usability guideline published by U.S. Department of Health and Human Services (HHS), making webpages highly visual before software development is very important, which is prototype design. Prototype produced an early, inexpensive and scaled down version of the webpages to check whether there was any problem with the current ideas in the early stage of webpage design (HHS, 2006). This was also a way to save time and money for both me and engineers. At this stage, a kind of low-fidelity prototype, a paper prototype, was developed to enable me and engineers to gain an overall view of the rudimentary webpages.

7.2.2. What was done at this stage and important questions met

The paper prototype was mainly designed by me. According to what had been discussed at the previous stage, nine kinds of webpages were designed through Microsoft Word®, including registration page, log-in page, password forgetting page, home page (four parts of contents, including three parts of "scales" and a part of "type 1 diabetes educational material"), a list of scales page, a specific scale with items page, a list of four sections of the type 1 diabetes material page, each section page with a list of “topics”, each “topic” page.

In terms of each page, the layout was important to consider because it could influence the expression of the information we intended to transmit. In this study, the webpages were developed for an educational purpose with standard layout to encourage participants to quickly find out what they needed to do. The patterns of the webpages’ layouts and some other key elements, such as colour, spacing and navigation, will be mentioned further.

- The patterns of the webpages’ layout

Grid layout and one-column layout were combined to be used during the design of the webpages. Usage of grid layout gave a sense of order to information or elements on each page and created clear connections between elements, such as home page (HHS, 2006). One-column layout with F-shaped pattern was widely used in this study, such as a list of scales page.

- Colour

Taking the target population into consideration, the dominant colours of the webpages were the white and blue of a daytime sky, which symbolises serenity.

- Spacing

Appropriate spacing was also used to make the webpages look simply and clean, and allow the contents of the webpages to be more acceptable.

- Navigation

In this study, the navigation was designed to be as simple, clear and consistent as possible, especially how to return to previous menu and home page (HHS, 2006).

• Icons

Icons were also designed to fit into the content or subtitles on the webpages. The overall style of the icons was kept consistent, including the size, colour and images on the icons (Zaphiris, 2005). Some meaningful stick figures were used to design the icons. For example, the icon of the third section "diabetes management" in the type 1 diabetes material was designed as a combination of a book, an apple, a person swimming, a drop of blood and an injection syringe, all of which were stick figures (as shown in Figure 7.11). These icons represented five components of diabetes management, that is, diabetes knowledge, diet, exercise, blood sugar monitoring, and insulin injection.

7.2.3. Impact on next stage

At the end of this stage, a rudimentary paper prototype was designed. As expected, the paper prototype played an essential role in the webpage design. More details were discussed and modified based on the paper prototype. In addition, communication between me and engineers was kept effectively.

7.3. Stage 3 (3/2019-5/2019): Software development

7.3.1. Basic introduction

At this stage, although most of the work was completed by the two engineers in China according to the paper prototype designed at the previous stage, communication between engineers and me still played an important part. Architecture of the mobile webpages and technical essentials of the webpage development will be mentioned further.

7.3.2. What was done at this stage?

(1) Architecture of the mobile webpages in this study

The mobile webpages were developed to help adolescents systematically study type 1 diabetes knowledge and improve confidence and adherence to manage their diabetes by using a smartphone. This was implemented by uploading a T1DM educational material to the webpages for participants to read. The architecture of the webpages is presented in Figure 7.2.

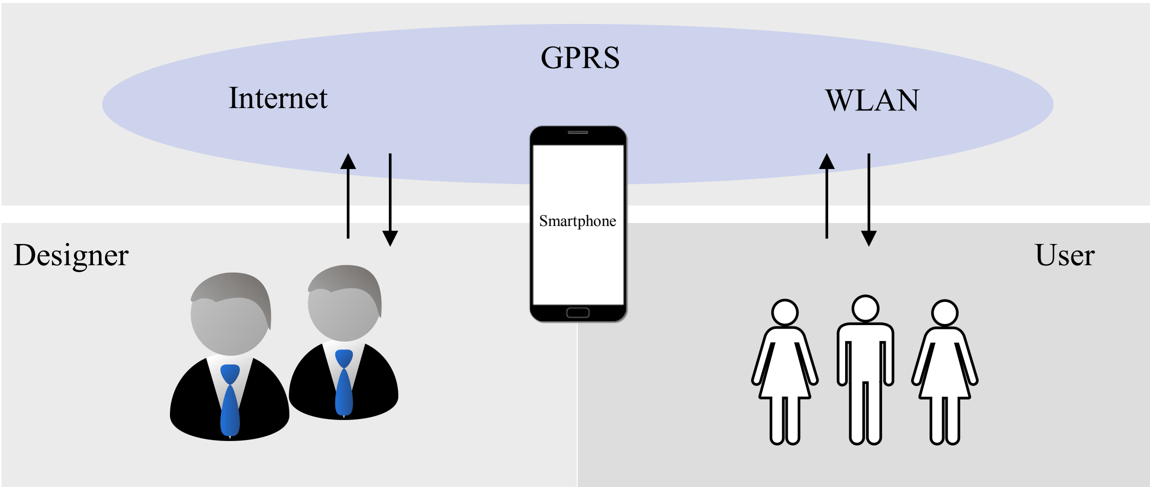


Fig 7.2. Architecture of the mobile webpage design in this study

(2) Technical essentials and development environment

1) Technical essentials

The webpages were developed through Browser/Server structure (B/S structure), or client/server model. In the client-server model, the client was considered as the front end and the server was considered as the back end. The front end and the back end were separate. Users did not need to download and set up any package but to input the website address into a mobile browser.

Front end (client-side)

The front end adopted the HTML5+CSS3 mode, which has been the most popular mode recently, combined with the mainstream framework “Bootstrap" for mixed development. Bootstrap is a free front-end framework for faster and easier web development. HTML5+CSS3 mode guaranteed that the webpages could be recognised and opened by most browsers of mobile phones. In addition, the Bootstrap framework was used to guarantee the consistency of the appearance of the webpages, which meant the webpages would look good all the time no matter of the size of a mobile screen. Dynamic interaction was enabled by using the jQuery framework which is the most widely used currently to avoid the compatibility issues of scripting language in the original JavaScript (Camden & Matthews, 2013).

Back end (server-side)

The back end was developed in Java language by using the mainstream framework “Springboot”. The service-oriented architecture (SOA) split the various functional units of the system (called services) to achieve loose coupling between services. A loose coupling system included two kinds of benefits. One benefit was its flexibility, that was, different functions could be implemented by a combination of different services. Another one was that the external programme would not be affected whether the internal structure and implementation of each service on the webpages were changed.

2) Development environment

IntelliJ IDEA is a Java integrated development environment (IDE) for developing computer/mobile software, which also has been recognised to be the fastest IDE tools. The webpages in this study were also developed with IntelliJ IDEA, which has been considered one of the best Java development tools for webpage development. It integrated a lot of practical and useful functions in the process of website development. Users could easily finish all the tasks on the mobile webpages. It was simple and powerful, and also maximised the development speed. IntelliJ IDEA also supported HTML, CSS and JavaScript, etc. System operation also used an open source container "TOMCAT", which was stable and convenient to operate (Camden & Matthews, 2013).

7.3.3. Result and important problems addressed

(1) The mobile webpages developed in this study

The webpages were developed in Chinese, which are attached in Appendix 12. The webpages were translated into English by me, which are presented from Figure 7.3 to Figure 7.37.

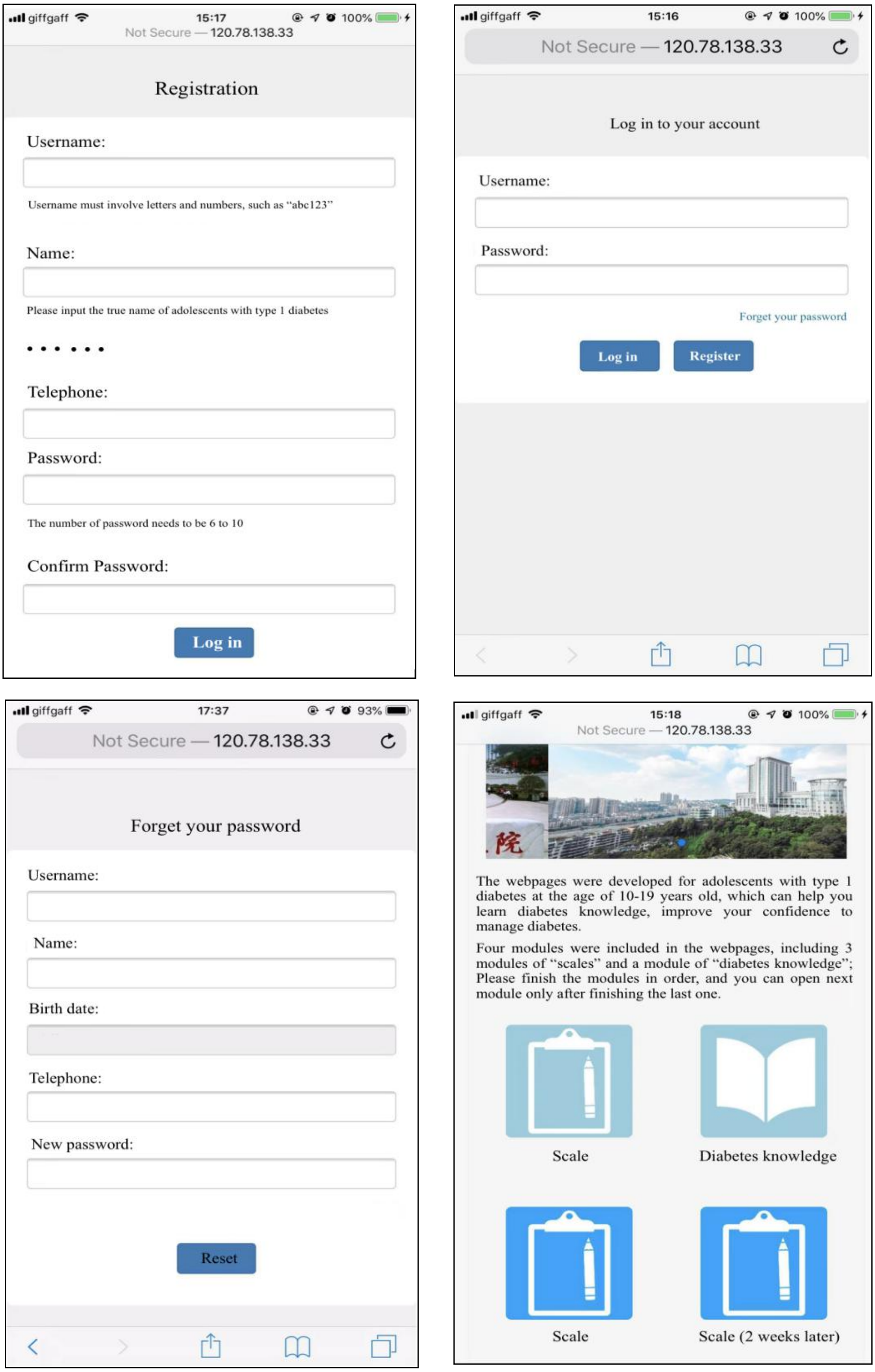
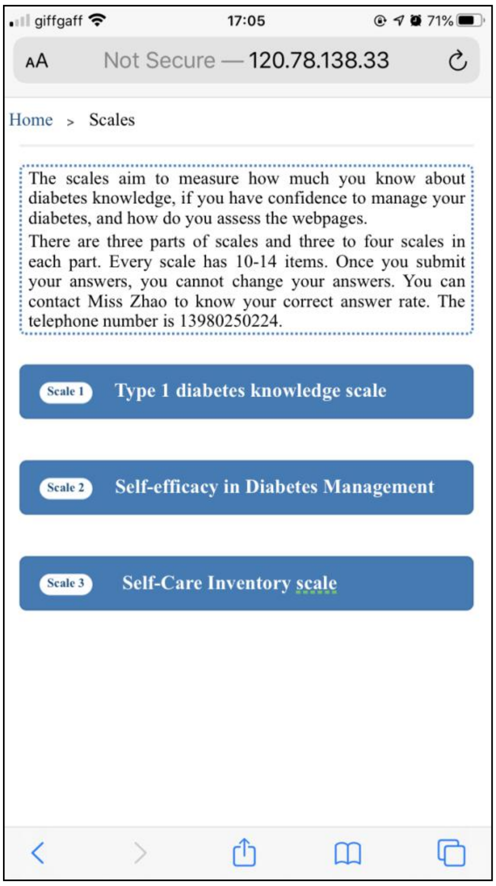
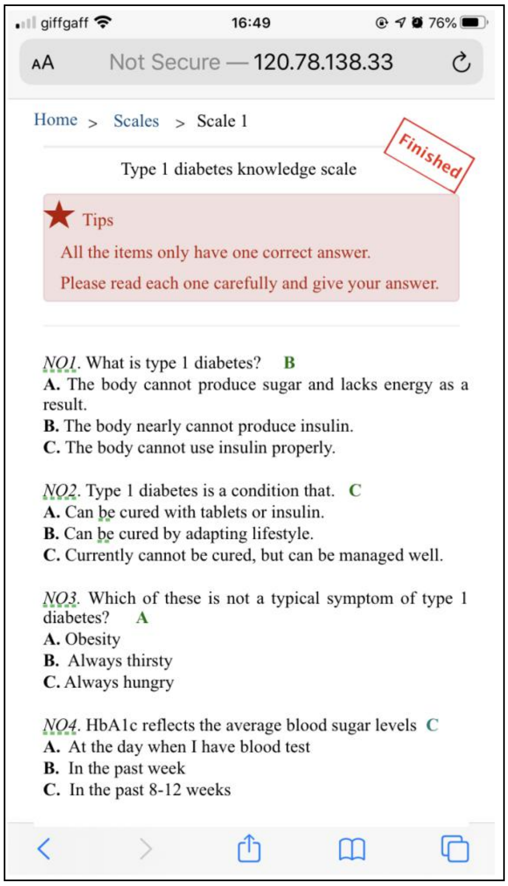
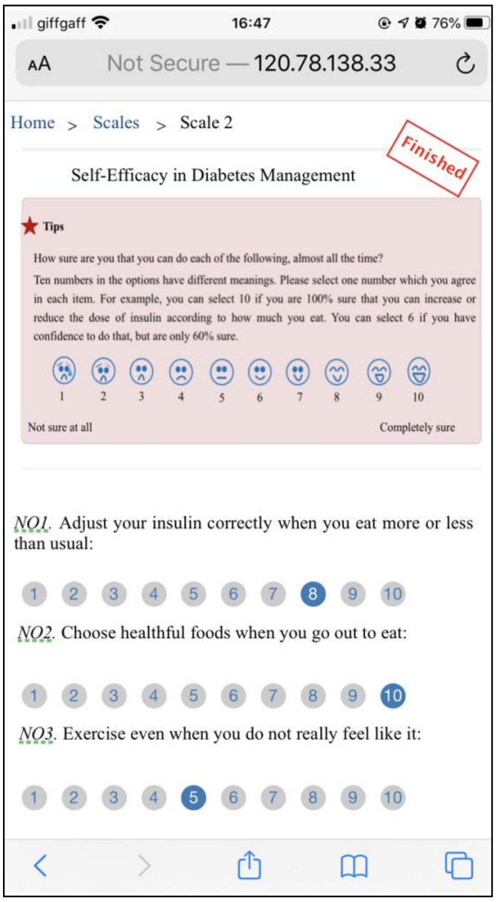


Fig 7.3-7.6. Log-in, registration, forgetting password, and home page







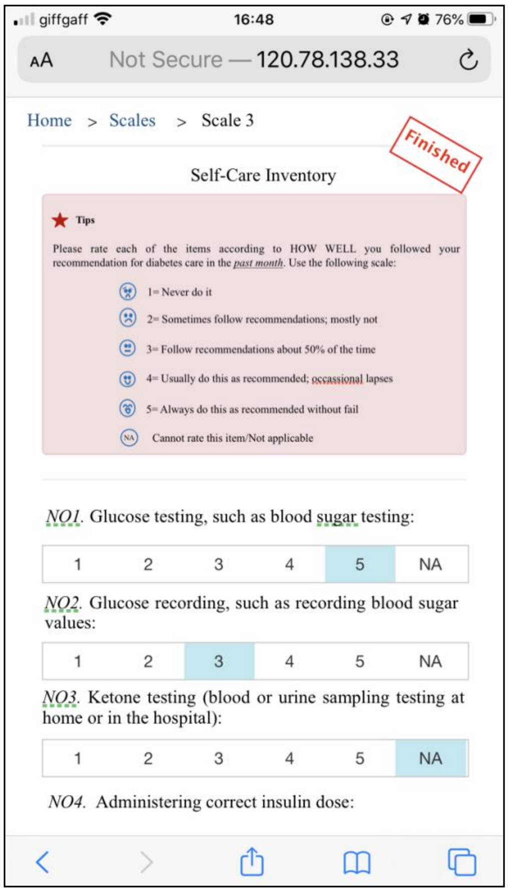


Fig 7.7-7.10. First "scale" part with the T1DK, SEDM, SCI scales

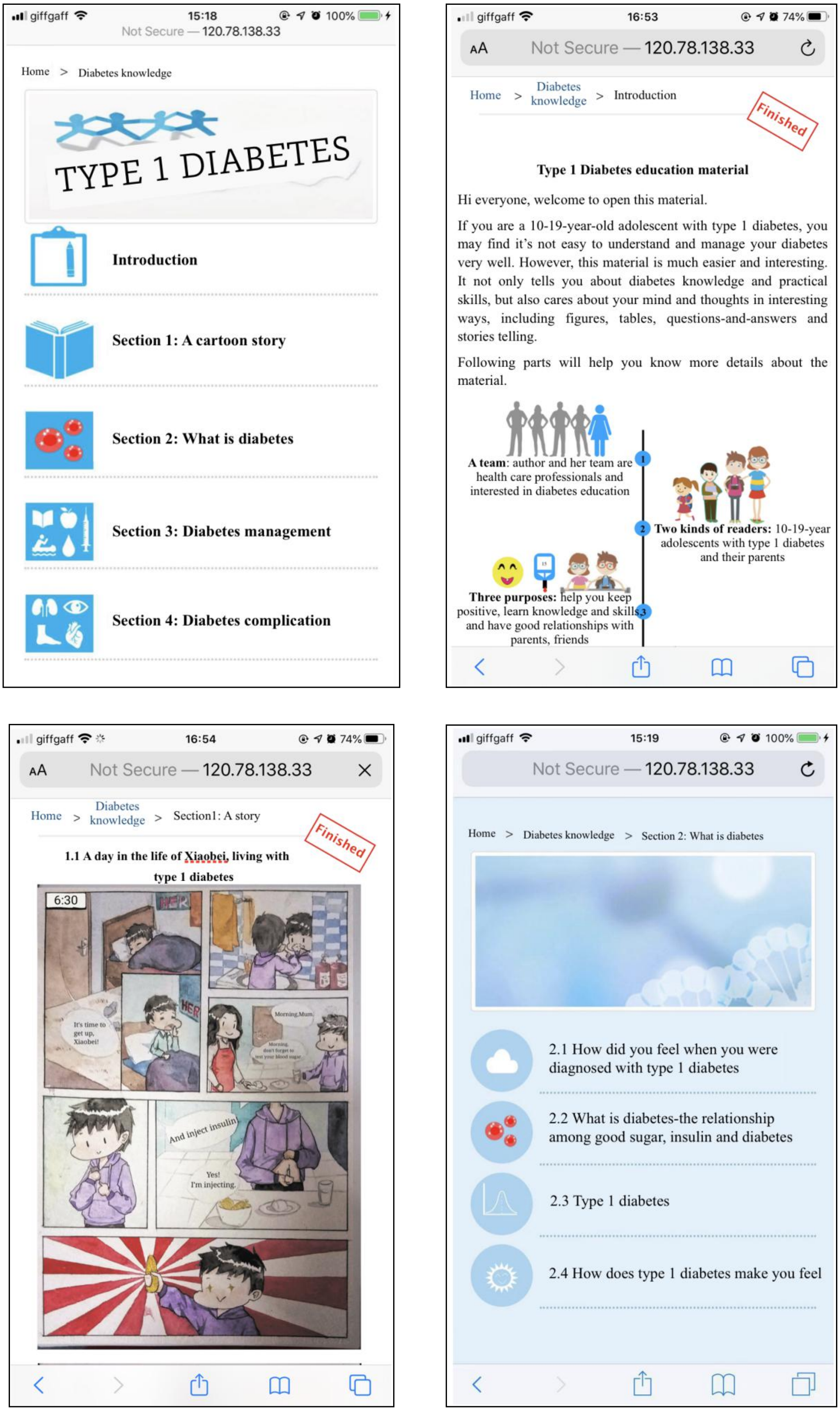


Fig 7.11-7.14. "Knowledge" part with four sections, introduction, section 1 and 2

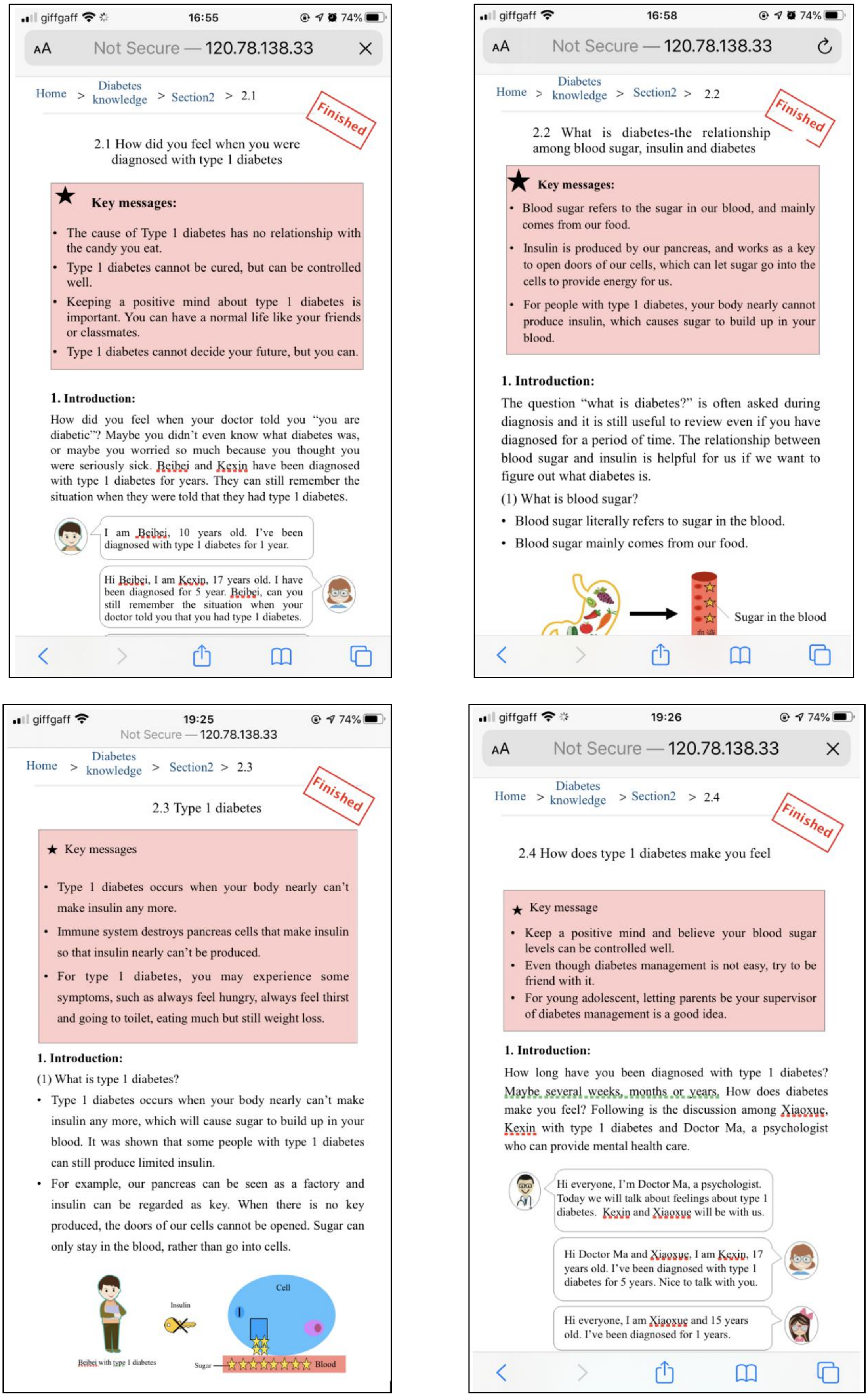
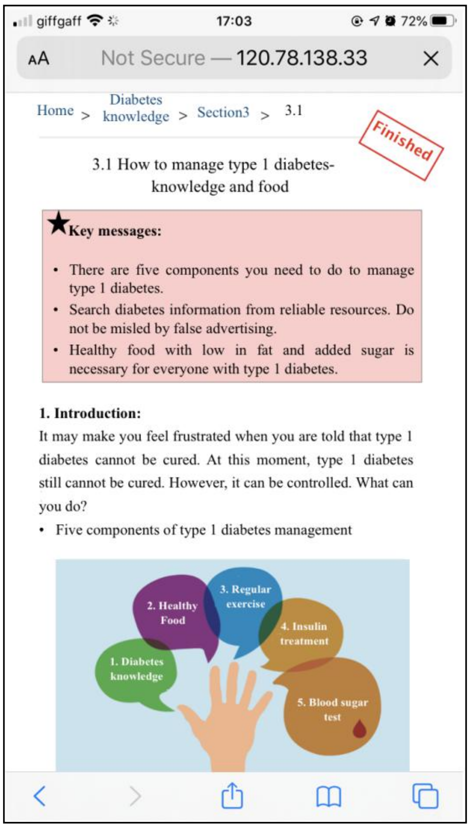
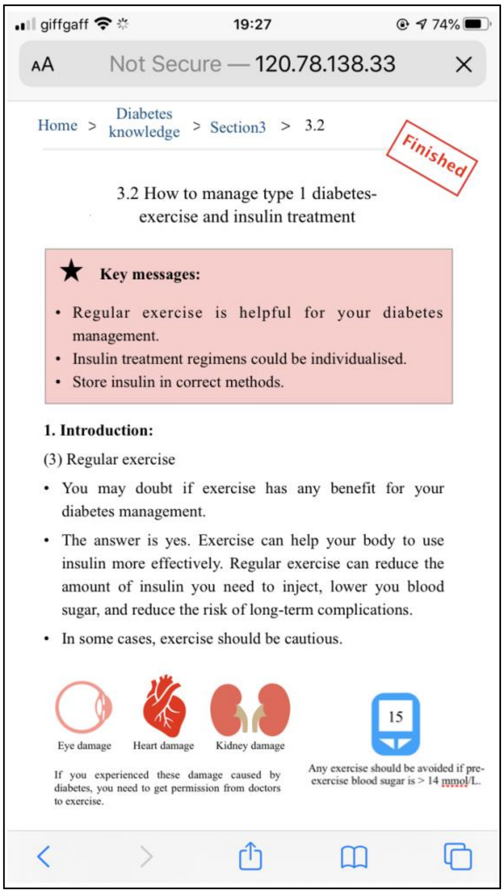


Fig 7.15-7.18. Four "topics" in section 2 of "knowledge" part (Topic 2.1-2.4)





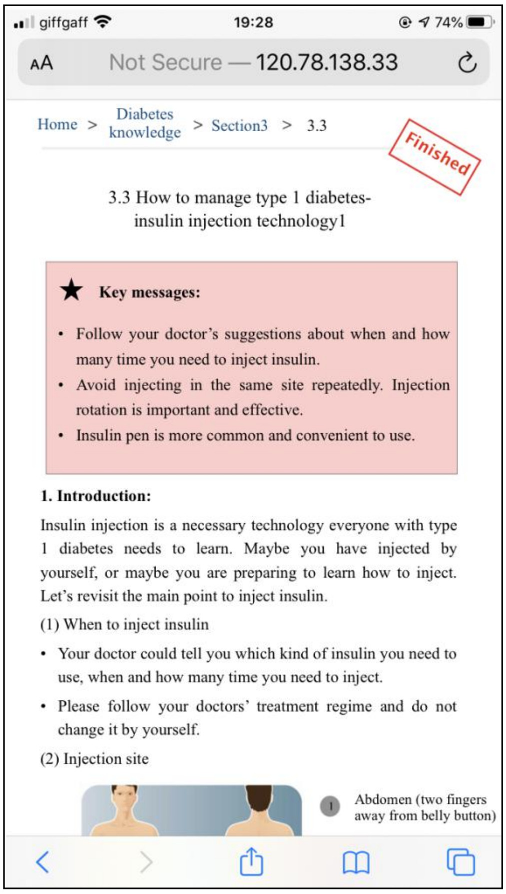


Fig 7.19-7.22. Section 3 of "knowledge" part (Topic 3.1-3.3)

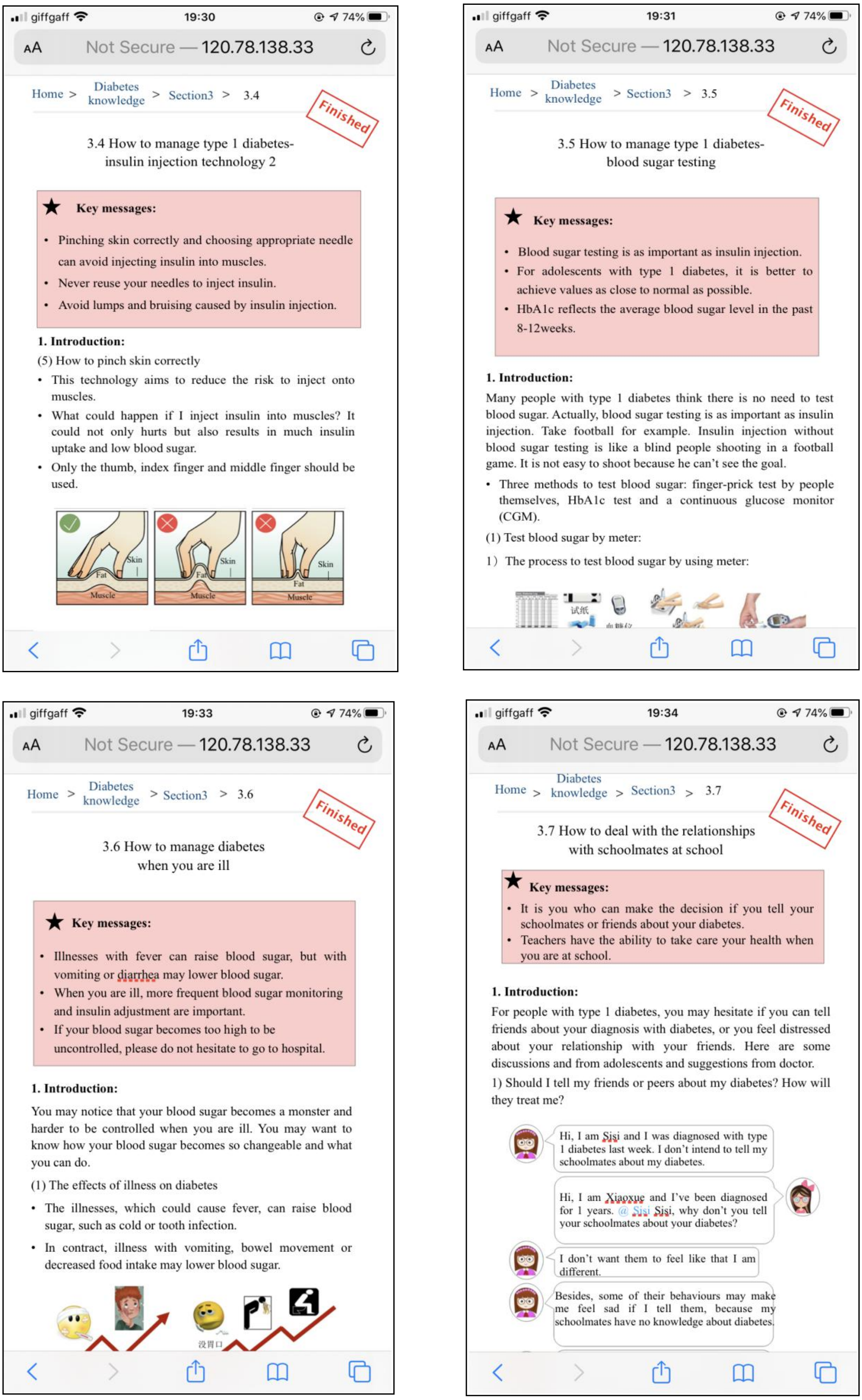


Fig 7.23-7.26. Section 3 of "knowledge" part (Topic 3.4-3.7)

Fig 7.27-7.30. Section 4 of "Diabetes knowledge" part (Topic 4.1-4.3)

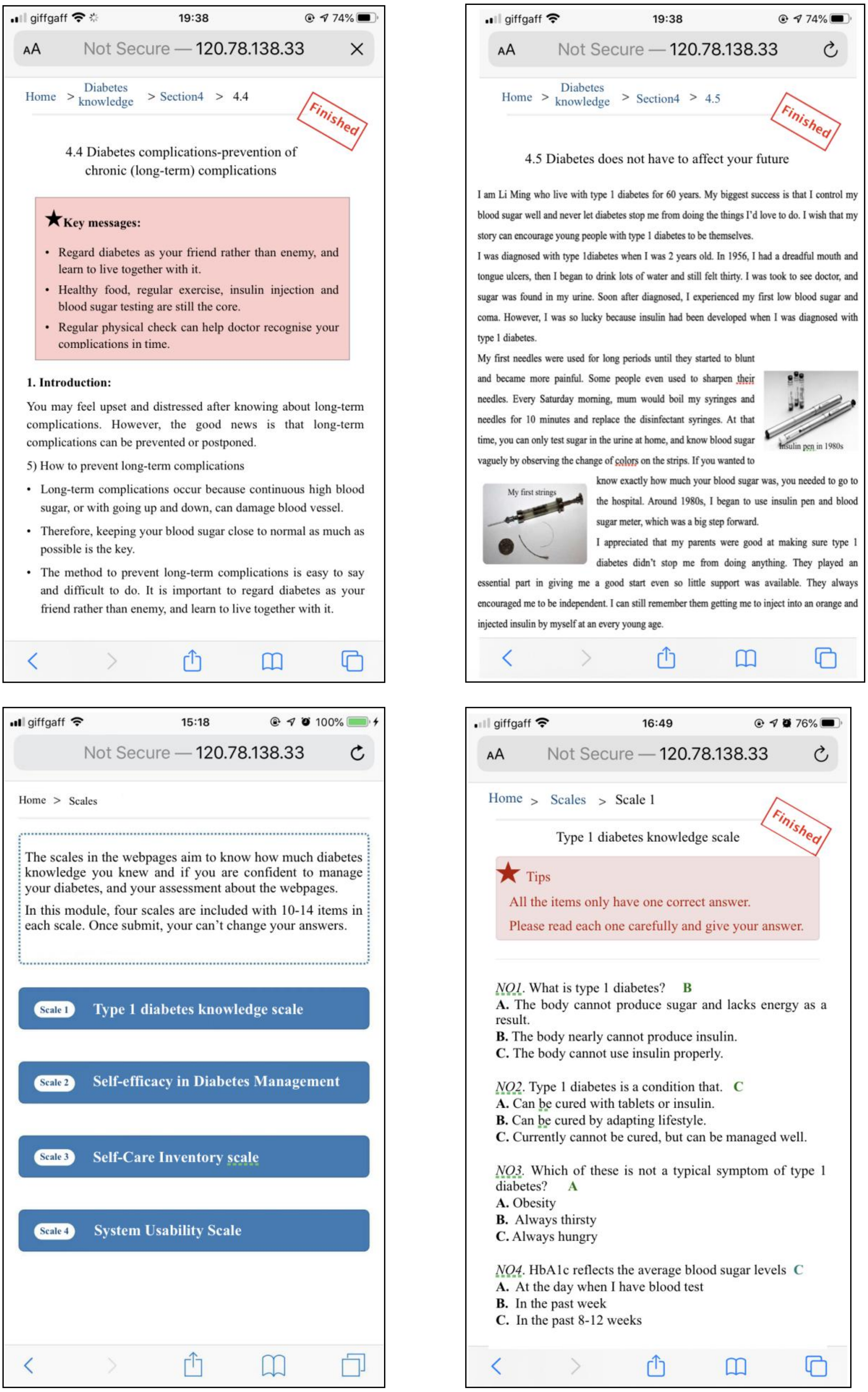


Fig 7.31-7.34. Section 4 of "knowledge" part (Topic 4.4-4.5) and "scale" parts

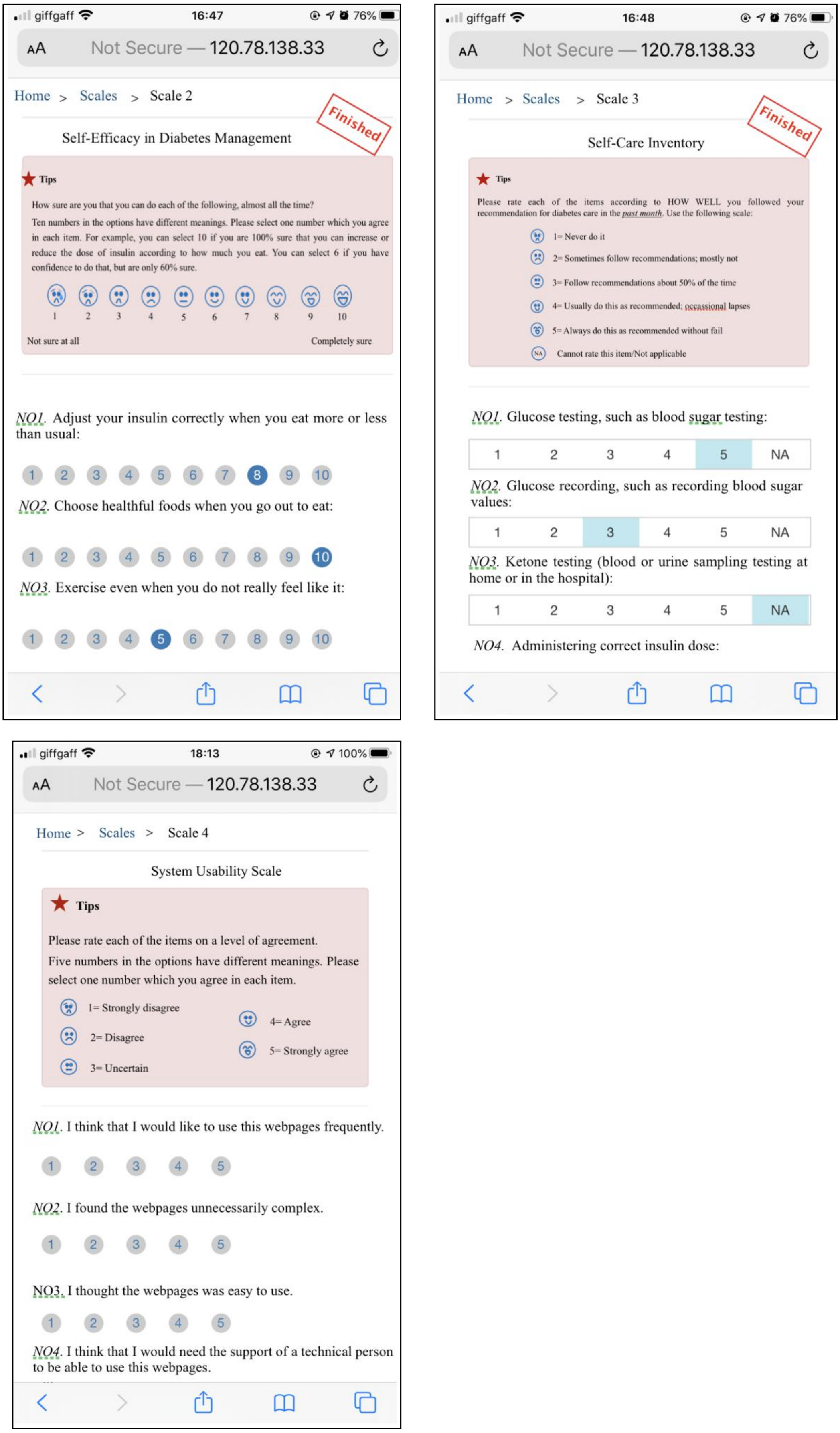


Fig 7.35-7.37. Second and third "scale" parts with scales (scale 2-4)

(2) Important problems addressed

• Instruction on the webpages

It was not necessary to add instructions to every webpage. As shown in Figures 7.33, some simple but necessary introductions were put on the webpages to guide participants and make them immediately aware what they needed to do. However, word count of the introductions was refined to the minimum because of the limited space on the mobile webpage and art of layout.

• How to achieve the functions with time limitation

As shown in Figure 7.6 “home page”, the last (third) part of “scale” should be completed two weeks after the second part of “scale” was finished. It was not easy to achieve except through the “back end”. At this stage, the server was set by the engineers so that participants could open the last part of the webpages at the right time. Otherwise, they could not open it and the system would remind them to open it two weeks later.

• How to keep the images on the webpages in order

The web-based T1DM educational material involved lots of images to help adolescents understand diabetes knowledge through visualisation of complicated or abstract definitions. However, the involvement of images would disorganise the layout of the material, that was, the images may not stay in the position where they should be. After communication, it was suggested that the words and images in every “topic” of this material could be exported to a PDF version. The PDF-version material was uploaded to the webpages, which guaranteed the words and images in the right position without negative influence on the appearance of pages.

• "Tips" part of the scales as an instruction

As mentioned in chapter 6, the "Tips" part with emoji was designed to help participants understand differences between levels of measurement in the three Likert scales, the Self-Efficacy in Diabetes Management, the Self-Care Inventory and the System Usability Scale. The "Tips" part was designed to stand still to make sure that participants can read the instructions and levels of the measurement all the time when they scrolled down to the end of the scales.

7.3.4. Impact on next stage

At this stage, webpage development was finished preliminarily. However, before publishing and using among participants, the webpages were tested by me and an adolescent with type 1 diabetes at next stage.

7.4. Stage 4 (5/2019): Software test

7.4.1. Basic introduction

It was necessary to test the webpages, which were newly developed in this study. This aimed to reduce any risks of affecting users' experience, and to decrease obvious deficits on the webpages by proactively eliminating problems (Borycki et al., 2011). In this study, it was a functional testing, which aimed to test the functionality of the webpages at this stage.

7.4.2. What was done at this stage and important problems met

After I tested the webpages without any issue, a 19-year-old adolescent was recruited to test the functionality of the webpages. The adolescent was asked to go through all of the webpages to check whether every webpage responded normally, or any could not be opened, or whether any button was not clickable, or whether there were any other problems. The data the adolescent completed were involved in the feasibility study.

There was one issue found about the scale page, in which the answers of items could not be selected or submitted by the adolescent. However, it did not happen on my iPhone®. Finally, the problem was resolved by changing to another mobile browser because of compatibility problems in some, such as QQ browser.

7.4.3. Impact on next stage

This stage was conducted to find problems which would affect functions of the webpages. It was essential to assure the webpages' normal operation in this study.

7.5. Stage 5 (5/2019-8/2019): Publishing and operation

7.5.1. Basic introduction

After testing, the webpages were published for participants to use. During operation, participants could still give feedback to the engineers about any problems encountered.

7.5.2. What was done at this stage and important problems met

The mobile webpages were developed in Chinese and published through the hyperlink http://120.78.138.33:8080/tnbdc/login.html (mobile webpages access in Chinese).

After operation, another problem occurred among several adolescents. They forgot password and failed to get it back from the "forget the password" page because they could not remember the exact information they completed before. They were suggested by the engineers to apply for a new account. There were no other problems found about the usage of the webpages developed in the study.

7.5.3. Impact on next stage

After being published, the webpages were accessible for participants who were recruited in the feasibility testing study from June 2019 to August 2019.

CHAPTER 8 DATA ANALYSIS AND RESULTS

In the feasibility study, 16 adolescents registered on the webpages to study the web-based T1DM educational material and completed up to four scales about diabetes knowledge, self-efficacy, adherence and webpage usability from June 2019 to August 2019. In this chapter, results are presented in four sections:

1) The first section summarises demographic characteristics of participants who took part in the feasibility study;

2) The second section includes results and narrative analysis of scales at scale level;

3) The third section presents results and narrative analysis of scales at item level;

4) The last section summaries the bullet points of the results in the feasibility study.

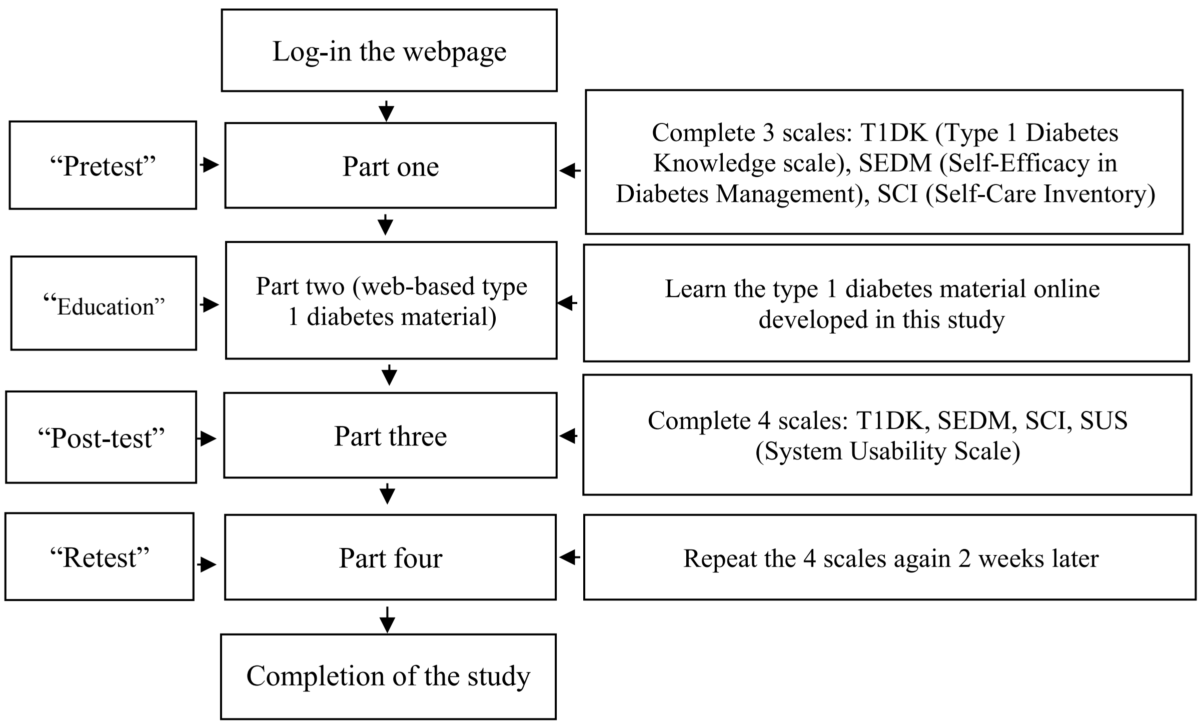


Fig 8.1. Completion of four parts of the webpages

8.1. Section 1: Demographic characteristics and completion status of participants

8.1.1. Process and result of participant recruitment

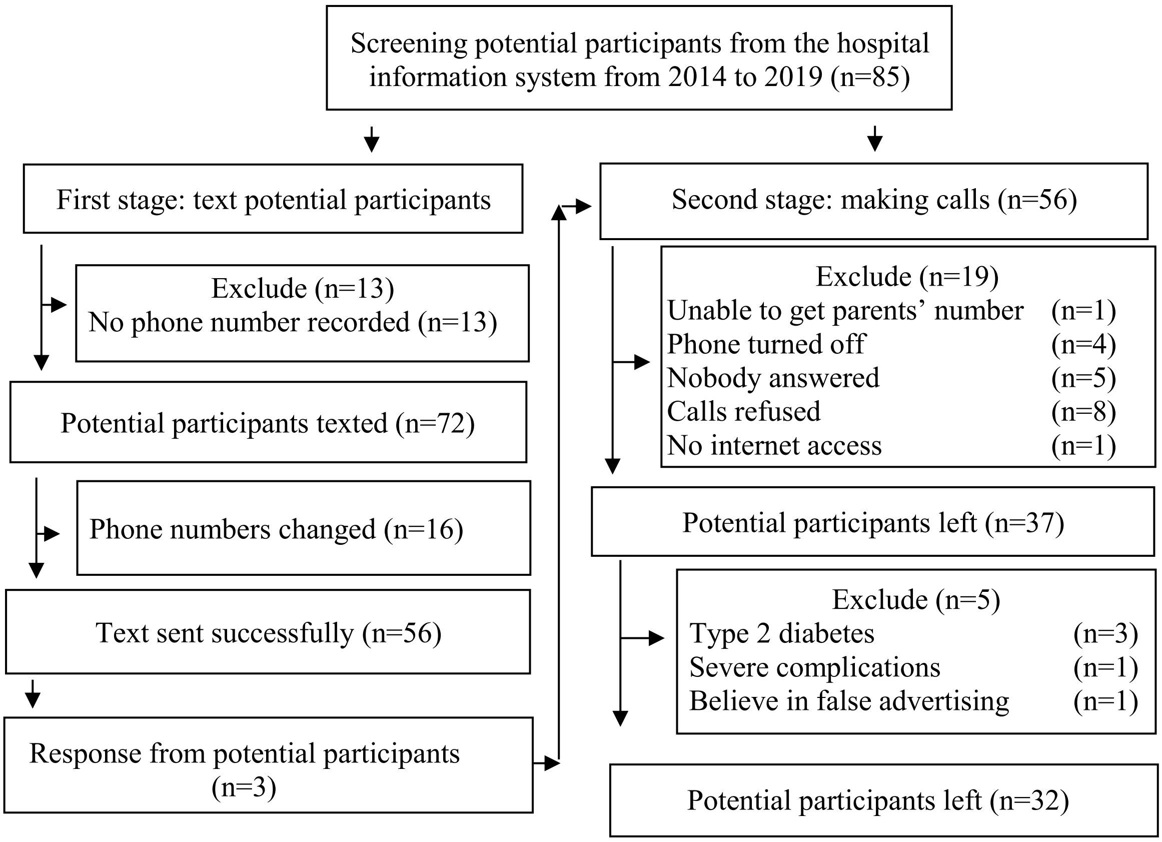


Fig 8.2. Flow chart about recruitment of participants in the feasibility study

1) Searching the hospital information system

After ethics approval was gained, the hospital information system was searched in the Affiliated Hospital of Southwest Medical University to find potential participants who met the inclusion criteria from 2014 to May 2019; 85 adolescents were found. Thirteen adolescents were excluded because no phone number was recorded, and 72 adolescents remained.

2) Texting potential participants

According to the initial ethics approval, SMS text was approved for use to recruit participants because it is a popular and not too coercive way for parents and adolescents.

Therefore, according to ethics, 72 adolescents were texted by using the recorded phone numbers, which mostly belonged to parents. Only 56 text messages were sent successfully from my mobile phone. Another 16 messages were not successfully sent, which was possibly due to changed phone numbers. My phone number belongs to the China Mobile Communications Corporation (CMCC), which is the largest mobile telecommunications corporation in China.

After texting those potential participants, my mobile phone could not send further texts as my phone number was reported, and the function of texting was removed. In China, the Ministry of Industry and Information Technology (MIIT) have a policy of reporting "illegal usage" of text messages that included pornography, violence, fraud, suggestions of terrorism, instigations to crime and gambling (TheTelegraphy, 2019). Therefore, my phone number was reported to the China Mobile and the MIIT because a parent thought it was a fraudulent message from a stranger. In addition, only three parents called or texted back to express interests to take part in the study.

3) Amendment of ethic approval

After communication with supervisors, I applied to the Ethics Committee about the change to recruitment of participants. An amendment form was quickly submitted and approved by the FHS Research Ethics Committee in Hull.

4) Making calls to potential participants

I began to call parents according to recorded numbers in the hospital information system. Twenty-four of 56 adolescents were excluded because they refused to take the phone calls, no answer to the calls, phone turning off, no internet access, type 2 diabetes (the diagnosis was type 1 diabetes in the hospital system), or believing in some false advertising (a parent bought so-called "wonder cures" for his child who was diagnosed with T1DM). The details are attached in Figure 9.2. Thirty-two parents consented for their children to take part in the study.

5) Waiting for response

After consenting to their children taking part in this study, parents stated they would discuss the study with their children. Once participates consented to the study, a hyperlink was sent to them. As a result, 16 adolescents registered on the webpages.

8.1.2. Demographic characteristics of participants who registered on the webpages

Sixteen adolescents who were aged between 10 to 19 years old and had been diagnosed with T1DM registered on the webpages in the feasibility testing study in June 2019. All the adolescents had been inpatients or outpatients in the Affiliated Hospital of Southwest Medical University, which is a university hospital in China. Demographic characteristics of the participants registered on the webpages are presented in Table 8.1.

Table 8.1. Demographic characteristics of participants registered online (N=16)

Items	Sub-items	Males		Females	
		N	M±SD	*N*	M±SD
Age	10~12 age group	0		2	11.5±0.71
	13~15 age group	3	14.33±0.58	2	14.00±1.41
	16~19 age group	2	16.00±0.00	7	17.57±1.13
Diabetes duration (months)	<1 year	2	3.00±0.00	3	2.00±1.73
	1~3 years	2	21.5±3.54	5	22.4±9.02
	>3 years	1	52.00±0.00	3	63.00±21.66
Education status (age)	Primary school	0		2	11.5±0.71
	Middle school	3	14.33±0.58	2	14.5±2.12
	High school	3	16.33±0.58	3	16.33±1.15
	College/university	0		3	18.67±0.58

Notes: In Chinese education system, there are 6 years in primary school, 3 years in middle school, 3 years in high school and 3-5 years in college or university.

As shown in Table 8.1, 11 participants were female. The 16 participants were aged from 11 to 19 years old with the mean age of 15.56 (*SD* 2.38) years, and more than half of participants (*N*=9) were in the age group of 16-19 years. Twelve participants had been diagnosed with T1DM for no more than three years. In terms of education status in China, participants who were in middle school and high school accounted for 68.75% (*N*=11).

8.1.3. Completion status of the webpages among participants

(1) Completion of four parts of the webpages

As shown in Figure 9.1, participants would be considered to have complete the study only if they had completed all four parts of the webpages, which were sequentially described as "Pretest" in Part one, "Education" in Part two, "Post-test" in Part three and "Retest" in Part four.

(2) Completion status of the webpages among participants

Although 16 participants registered on the webpages in the feasibility study, four were lost to follow up after registration without any more log-in. Six participants fully completed the study (all four parts of the webpages) with a completion rate of 37.5%. The completion status of every part of the webpages among participants are presented in Figure 8.3.

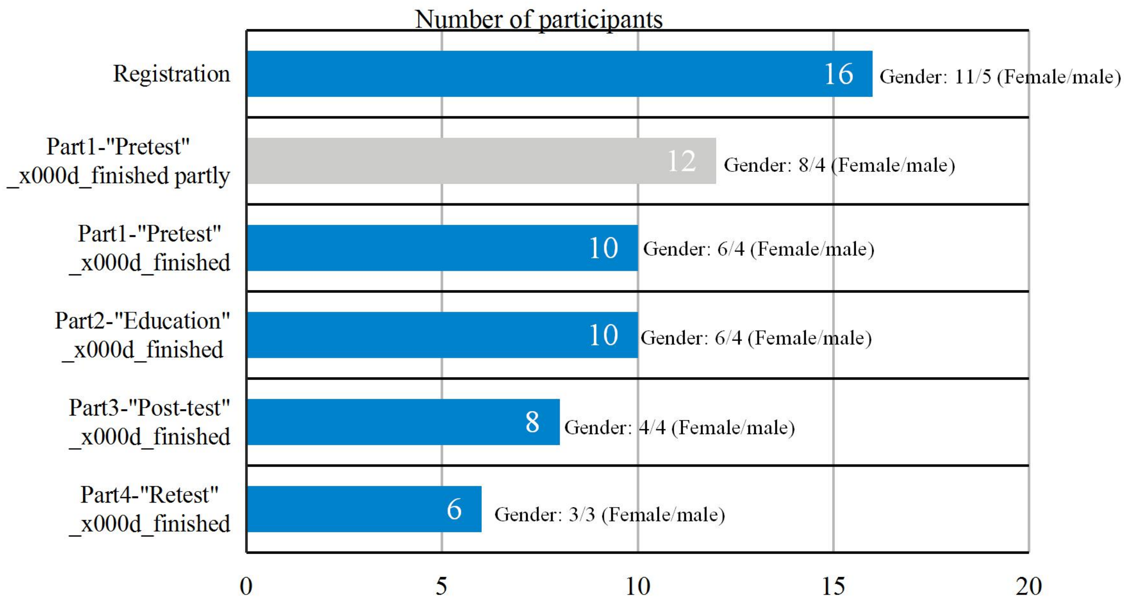


Fig 8.3. Completion status of the webpages and age and gender distribution

As presented in Figure 8.3, completion rates of the webpages were 62.5% (N=10) in "Pretest", 62.5% (N=10) in "Education", 50% (N=8) in "Post-test" and 37.5% (N=6) in "Retest", separately. Two participants partially completed "Pretest", which is presented with a light grey bar in Figure 9.3.

In addition, 11 female adolescents registered on the webpages and only three completed the study with a completion rate of 27%. Male adolescents appeared more likely to complete the study with a higher completion rate of 60% (N=3) although only five male adolescents registered on the webpages. In terms of age difference, the mean ages of participants who completed the webpages slightly decreased from 16 (*SD* 2.21) years in "Pretest" to 15.33 (*SD* 2.50) years in "Retest" in Figure 8.3. Participants' loss to follow up in three age groups are presented throughout the study in Figure 8.4.

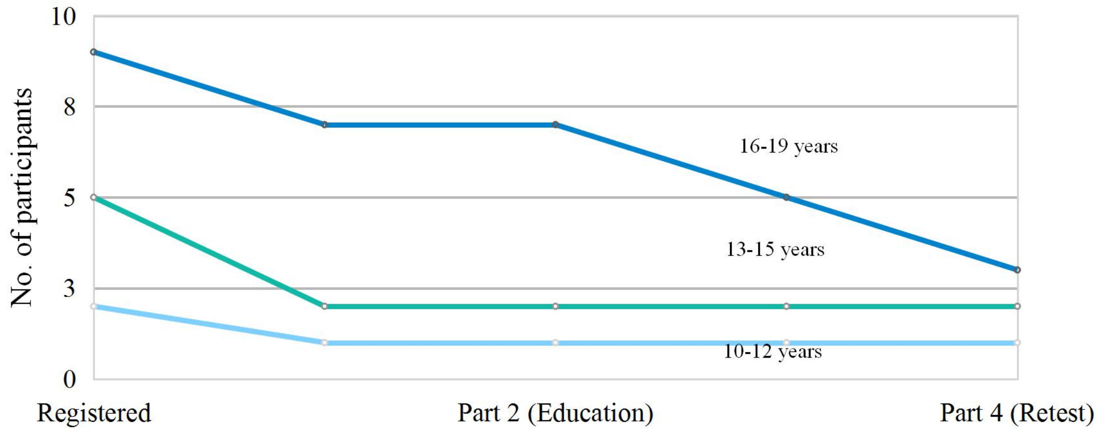


Fig 8.4. Participants' lost to follow up in three age groups

As shown in Figure 8.4, the highest rate of loss to follow-up was among adolescents at the age group of 16 to 19 years from registration to "Retest". Older adolescents aged from 16-19 years old seemed more likely to be lost to follow-up in this study.

8.2. Section 2: Narrative analysis and results of four scales at scale level

8.2.1. Details of adolescents who registered on the webpages

The 16 adolescents are coded from A1 to A16 based on their usernames. Table 8.2 also shows every participant's completion status of the webpages from registration to "Retest". A tick indicated full completion of a certain part in Table 8.2, and a list of scales indicated a partial completion. Six adolescents (A1, A2, A5, A6, A8, A10) fully completed all four parts of the webpages.

Table 8.2. Details and completion status of participants in the feasibility study

Code	Age	Gender	Diabetes duration (Months)	Education status	Completion status of the webpages				
					Registration	"Pretest" (T1DK, SEDM, SCI)	"Education"	"Post-test" (T1DK/SEDM/SCI/SUS)	"Retest" (T1DK/SEDM/SCI/SUS)
A1	14	Male	3	Middle school	√	√	√	√	√
A2	12	Female	18	Primary school	√	√	√	√	√
A3	17	Female	1	High school	√	√	√	√	
A4	15	Female	51	High school	√	T1DK scale			
A5	14	Male	3	Middle school	√	√	√	√	√
A6	17	Female	17	High school	√	√	√	√	√
A7	13	Female	1	Middle school	√	T1DK/SEDM scales			
A8	19	Female	88	College/University	√	√	√	√	√
A9	16	Female	50	Middle school	√	√	√	T1DK scale	
A10	16	Male	52	High school	√	√	√	√	√
A11	19	Female	27	College/University	√	√	√	T1DK/SCI/SUS scales	
A12	16	Male	19	High school	√	√	√	√	
A13	15	Female	24	Middle school	√				
A14	18	Female	36	College/University	√				
A15	17	Female	4	High school	√				
A16	11	Female	14	Primary school	√				

8.2.2. Narrative analysis of the four scales participants completed at scale level

To compare results of the four scales participants completed, correct answer rates of the Type 1 Diabetes Knowledge (T1DK) scale, and the mean and standard deviation (M±*SD*) of all the items in the Self-Efficacy in Diabetes Management (SEDM) scale and the Self-Care Inventory (SCI) scale were calculated among every participant and summarised in Table 8.3, as well as an adjective rating system with a range of 0 to100 in the System Usability Scale (SUS) (Brooke, 1996).

Table 8.3. Results of the four scales participants completed at scale level

Participant (age) (Fmale/male=F/M)	"Pretest"			"Post-test"							"Retest"							
	Diabetes knowledge	Self-efficacy	Adherence	Diabetes knowledge		Self-efficacy		Adherence		Webpage usability	Diabetes knowledge		Self-efficacy		Adherence		Webpage usability	
	T1DK 0~100 (%)	SEDM 0~10 M±*SD*	SCI 0~5 M±*SD*	T1DK 0~100% %		SEDM 0~10 M±*SD*		SCI 0~5 M±*SD*		SUS 0~100 Rating	T1DK 0~100% %		SEDM 0~10 M±*SD*		SCI 0~5 M±*SD*		SUS 0~100 Rating	
A1 14 year/M	58.33%	9.40±0.52	4.57±0.51	75%	↑	9.40±0.52	↔	4.36±0.50	↓	62.5 (OK)	75 %	↔	8.80±0.42	↓	4.29±0.47	↓	65 (OK)	↑
A2 12 years/F	75%	8.60±1.51	3.86±1.46	50%	↓	8.80±0.92	↑	3.79±1.19	↓	85 (Good)	41.67%	↓	7.50±1.35	↓	3.79±1.05	↔	80 (Good)	↓
A3 17 years/F	91.67%	8.80±1.14	3.71±1.33	100%	↑	8.10±0.74	↓	3.92±1.19	↑	65 (OK)								
A4 15 years/F	100%																	
A5 14 years/M	80%	10.00±0.00	4.62±0.87	90%	↑	10.00±0.00	↔	4.62±1.12	↔	80 (Good)	70 %	↓	9.60±1.26	↓	4.21±1.58	↓	100 (Best imaginable)	↑
A6 17 years/F	75%	5.90±1.79	3.29±1.44	91.67 %	↑	6.50±1.51	↑	2.86±1.35	↓	95 (Excellent)	100 %	↑	6.80±2.04	↑	3.14±0.95	↑	93 (Excellent)	↓
A7 13 years/F	58.33%	6.10±3.00																
A8 19 years/F	80%	8.10±0.99	3.07±1.73	80%	↔	7.80±0.79	↓	3.29±1.82	↑	87.5 (Excellent)	100 %	↑	8.00±0.67	↑	3.50±1.34	↑	95 (Excellent)	↑
A9 16 years/F	75%	9.20±1.03	4.07±1.14	75%	↔													
A10 16 years/M	75%	5.00±3.65	3.00±1.11	91.67 %	↑	6.90±1.20	↑	3.21±1.37	↑	87.5 (Excellent)	75 %	↓	8.10±1.73	↑	3.54±1.27	↑	100 (Best imaginable)	↑
A11 19 years/F	50%	6.99±1.66	3.21±1.05	66.67 %	↑			3.36±1.28	↑									
A12 16 years/M	83.33%	3.90±1.37	3.38±1.26	83.33 %	↔	4.80±0.92	↑	3.23±1.30	↓									

- Grey cells indicate the lowest scores, and blue cells indicate the highest scores in a scale in a certain stage of the study.
- Red arrows mean decrease, green arrows mean increase, and black left-right arrows mean the same scores in the same scale from Part one "Pretest" to Part three "Pos-test" or from Part three "Post-test" to Part four "Retest".

The "correct answer rates" of the Type 1 Diabetes Knowledge (T1DK) scale ranged from 50% in A11 (a 19-year girl) to 100% in A4 (a 15-year girl) in "Pretest". In "Post-test", nine of ten participants got the same or increased scores, however, the correct answer rates decreased by 25% to 50% in A2 who was a 12-year girl, which continued to reduce by 8.33% to 41.67% in "Retest". Another two adolescents (A5, a 14-year boy; A10, a 16-year boy) also got decreased scores in "Retest", compared with "Post-test".

In terms of the Self-Efficacy in Diabetes Management (SEDM) scale, A12 (a 16-year boy) scored the lowest self-efficacy (3.90 SD 1.37) in "Pretest", which was far lower than the second lowest score (5.00 SD 3.65) in A10 (a 16-year boy). However, A12 had 83.33% correct answers in the T1DK scale in "Pretest". The highest self-efficacy (10.00 SD 0) was scored by A5 (a 14-year boy) who had a relatively lower correct answer rate on diabetes knowledge (80%) in "Pretest". Six of eight participants scored the same or increased self-efficacy in "Post-test" except A3 (a 17-year girl) and A8 (a 19-year girl). In "Retest", three (A1, a 14-year boy; A2, was a 12-year boy; A5, a 14-year boy) of six participants got reduced scores in the SEDM scale, compared with "Post-test".

In the Self-Care Inventory (SCI) scale, a 16-year boy (A10) scored the lowest adherence (3.00 SD 1.11) who also scored the second lowest self-efficacy in the SEDM scale in "Pretest", although he had a relatively higher correct answer rate (75%) in the T1DK scale. The highest adherence in the SCI scale was given by A5 (a 14-year boy) who also scored the highest self-efficacy in the SEDM scale in "Pretest". However, A5 did not score highest on diabetes knowledge, which was 80% in "Pretest". In "Post-test", five (A3, A5, A8, A10, A11) of nine participants scored the same or higher levels of adherence. However, in "Retest", two (A1, A5) of six participants scored reduced adherence in the SCI scale, compared with "Post-test".

As far as webpage usability, nine participants completed the System Usability Scale (SUS) scale in “Post-test”, in which the scores ranged from 62.5 with a meaning of “OK” in A1 (a 14-year boy) to 95 with a meaning of “Excellent” in A6 (a 17-year girl). Furthermore, A6 also got higher scores on diabetes knowledge, but lower self-efficacy in the SEDM scale and lower adherence in the SCI scale than A1 in both “Pretest” and “Post-test”. Although two (A2, A6) of six participants gave lower scores in “Retest”, another two participants (A5, a 14-year boy; A10, a 16-year boy) gave the highest score of “100” with the meaning of “Best imaginable”.

8.2.3. Narrative analysis of diabetes knowledge among participants in subgroups

Twelve adolescents completed the Type 1 Diabetes Knowledge (T1DK) scale with a mean correct answer rate of 75.14% in “Pretest”. The mean correct rate increased to 80.33% among 10 participants in “Post-test” (two participants did not complete beyond Part one), reducing to 76.95% among six participants in “Retest”. This was the overall trend of changes on diabetes knowledge throughout the study. To explore whether there were differences on diabetes knowledge among different groups of participants at different stages of the study, subgroup review was conducted in Table 8.4.

Table 8.4. Results of the Type 1 Diabetes Knowledge Scale in subgroups

Items	Subitems	Part 1 "Pretest"		Part 3 "Post-test"		Part 4 "Retest"		Comparison between stages	
		N	Mean (%)	*N*	Mean (%)	*N*	Mean (%)	Part 1-3	Part 3-4
Gender	Female	8	75.63%	6	77.22%	3	80.56%	Increase	
	Male	4	74.17%	4	85%	3	73.33%	Increase	Decrease
Age group	10~12 years	1	75%	1	50%	1	41.67%	Decrease	
	13~15 years	4	74.17%	4	82.5%	4	72.5%	Increase	Decrease
	16~19 years	7	75.71%	7	84.05%	3	91.67%	Increase	
Diabetes duration	<1year	4	72.08%	3	88.33%	2	72.5%	Increase	Decrease
	1~3 years	4	70.83%	4	72.92%	2	70.84%	Increase	Decrease
	>3 years	4	82.5%	3	82.22%	2	87.5%	Constant	Increase
Education status	Primary school	1	75%	1	50%	1	41.67%	Decrease	
	Middle school	4	67.92%	3	80%	2	72.5%	Increase	Decrease
	High school	5	85.0%	4	91.7%	2	87.5%	Increase	Decrease
	College/University	2	65%	2	73.34%	1	100%	Increase	

(1) Narratives of changes in diabetes knowledge between stages (Part 1-3 and Part 3-4)

As shown in Table 8.4, means scores of diabetes knowledge increased from "Pretest" to "Post-test" but reduced in "Retest" in most subgroups, which was consistent with the overall trend.

However, females; those in the 16-19 age group; and those in the college/university answered the T1DK scale with increased correct rates from "Pretest" to "Retest". On the contrary, one participant (A2, a 12-year girl in primary school) had decreasing scores throughout the study and she had been diagnosed for only 18 months. By reviewing the results she completed in the T1DK scale, four items were answered correctly in "Pretest" but answered incorrectly in "Post-test" or "Retest".

(2) Narratives of changes of diabetes knowledge among subgroups

There was no gender difference found on diabetes knowledge among the participants. Although correct answer rates of the T1DK scale were similar among female and male participants in “Pretest”, the male participants answered the scale with higher correct rates in “Post-test”, and the females got higher correct rates in “Retest”.

Correct answer rates of the T1DK scale increased as the age group increased in this study, which meant the participants who were in the 10-12 age group answered the T1DK scale with the lowest correct answer rates and those in the 16-19 age group got the highest correct rates at all three stages.

The participants who had been diagnosed with T1DM for one to three years answered the T1DK scale with the lowest mean correct rates at all three stages of the study. Those who had been diagnosed for more than three years generally scored the highest correct answer rates, which were more than 80% at all three stages.

There was no positive relationship between diabetes knowledge and education status in this study (within caveat of the small sample). The correct answer rates among participants in high school generally remained to be the highest, which followed by those who were in middle school. Two participants (A8, A11 who were 19-year girls) in the college or university got relatively lower correct answer rates, especially in “Pretest” and “Post-test”, which needs to be interpreted with caution because of the small sample size.

8.2.4. Narrative analysis of self-efficacy among participants in subgroups

In “Pretest”, 11 participants completed the Self-Efficacy in Diabetes Management (SEDM) scale with a mean of individuals’ scores of 7.45 (*SD* 2.00). The mean increased to 7.79 (*SD* 1.69) among eight participants in “Post-test”, increasing to 8.13 (*SD* 0.98) among six participants who completed the Part four “Retest”. This was the overall trend of self-efficacy in the SEDM scale at three stages. Subgroup review was conducted in the SEDM scale to explore whether there were different levels of self-efficacy existing in different groups of participants at different stages in Table 8.5.

Table 8.5. Results of the Self-Efficacy in Diabetes Management scale in subgroups

Items	Sub-items	Part 1 "Pretest"		Part 3 "Post-test"		Part 4 "Retest"		Comparison between stages	
		N	Mean±*SD*	*N*	Mean±*SD*	*N*	Mean±*SD*	Part 1-3	Part 3-4
Gender	Female	7	7.66±2.06	4	7.80±1.30	3	7.43±1.50	Increase	Decrease
	Male	4	7.08±3.29	4	7.78±2.24	3	8.83±1.37	Increase	
Age group	10~12 years	1	8.60±1.51	1	8.80±0.92	1	7.50±1.35	Increase	Decrease
	13~15 years	3	8.50±2.43	2	9.70±0.47	2	9.20±1.01	Increase	Decrease
	16~19 years	7	6.83±2.58	5	6.82±1.56	3	7.63±1.65	Maintained	Increase
Diabetes duration	<1year	4	8.58±2.17	3	9.17±0.95	2	9.20±1.01	Increase	
	1~3 years	4	6.33±2.30	3	6.70±2.00	2	7.15±1.73	Increase	
	>3 years	3	7.43±2.84	2	7.35±1.09	2	8.05±1.28	Decrease	Increase
Education status	Primary school	1	8.60±1.51	1	8.80±0.92	1	7.50±1.35	Increase	Decrease
	Middle school	4	8.64±2.18	2	9.70±0.47	2	9.20±1.01	Increase	Decrease
	High school	4	5.90±2.82	4	6.58±1.62	2	7.45±1.96	Increase	
	College/University	2	7.50±1.47	1	7.78±0.79	1	8.00±0.67	Increase	

(1) Narratives of changes of self-efficacy between stages (Part 1-3, Part 3-4)

In the Self-Efficacy in Diabetes Management (SEDM) scale, self-efficacy continuously increased in five of 12 subgroups from "Pretest" to "Retest", which reflected the overall trend of the mean scores. However, in another five subgroups, scores of self-efficacy in the SEDM scale increased in "Post-test", but reducing in "Retest".

(2) Narratives of changes of self-efficacy in the two scales among subgroups

Lower scores in the SEDM scale were given by male participants in "Pretest" and "Post-test", however, males scored a greatly higher self-efficacy than females in

“Retest”. Participants in the 13-15 age group scored the highest self-efficacy in the SEDM scale throughout the study, and those in the 16-19 age group gave the lowest scores of self-efficacy.

Participants who had been diagnosed less than one year scored the highest self-efficacy in the SEDM scale throughout the study. Those diagnosed between one to three years scored the lowest self-efficacy at all three stages. Participants in middle school scored the highest self-efficacy in the SEDM scale, which followed by those in primary school, then by those in the college/university. Participants in high school gave the lowest scores.

8.2.5. Narrative analysis of adherence among participants in subgroups

In the Self-Care Inventory (SCI) , the mean of individuals’ scores was 3.68 (*SD* 0.59) in “Pretest”, which slightly reduced to 3.63 (*SD* 0.58) in “Post-test”, then increasing to 3.74 (*SD* 0.44) in “Retest”. Subgroup review was also conducted in Table 8.6.

Table 8.6. Results of the Self-Care Inventory scale in subgroups

Items	Subitems	Part 1 "Pretest"		Part 3 "Post-test"		Part 4 "Retest"		Comparison between stages	
		N	Mean±*SD*	*N*	Mean±*SD*	*N*	Mean±*SD*	Part 1-3	Part 3-4
Gender	Female	6	3.54±1.38	5	3.43±1.40	3	3.48±1.13	Decrease	Increase
	Male	4	3.80±1.19	4	3.85±1.27	2	4.02±1.21	Decrease	Increase
Age group	10~12 years	1	3.86±1.46	1	3.79±1.19	1	3.79±1.05	Decrease	The same
	13~15 years	2	4.59±0.69	2	4.48±0.85	2	4.25±1.14	Decrease	
	16~19 years	7	3.39±1.32	6	3.30±1.39	3	3.39±1.18	Decrease	Increase
Diabetes duration	<1year	3	4.29±1.03	3	4.30±0.99	2	4.25±1.14	Increase	Decrease
	1~3 years	4	3.44±1.30	4	3.31±1.29	2	3.46±1.04	Decrease	Increase
	>3 years	3	3.38±1.41	2	3.27±1.31	2	3.52±1.28	Decrease	Increase
Education status	Primary school	1	3.86±1.46	1	3.19±1.19	1	3.79±1.05	Decrease	Increase
	Middle school	3	4.41±0.89	2	4.48±0.85	2	4.25±1.14	Increase	Decrease
	High school	4	3.35±1.28	4	3.30±1.33	2	3.33±1.11	Decrease	Increase
	College/University	2	3.14±1.41	2	3.32±1.54	1	3.50±1.34	Increase	

(1) Narratives of changes of adherence between stages (Part 1-3, Part 3-4)

Adherence in the Self-Care Inventory (SCI) scale decreased in eight of 12 subgroups in Part three "Post-test" but increased in Part four "Retest". Furthermore, the participants in the college/university group continuously scored increased self-efficacy from "Pretest" to "Retest". On the contrary, two boys (A1, A5) in the 13-15 age group scored continually decreased adherence. However, they still gave the highest adherence scores in the SCI scale, as well as the highest self-efficacy in the SEDM scale.

(2) Narratives of changes of adherence among subgroups

Male participants scored higher adherence in the SCI scale than females at all three stages. Participants in the 13-15 age group scored the highest adherence throughout the study, and those in the 16-19 age group gave the lowest scores of adherence. This was congruent with the result of self-efficacy in the SEDM scale.

Participants who had been diagnosed less than one year scored the highest adherence in the SCI scale throughout the study, which was congruent with the result of self-efficacy in the SEDM scale. However, results of the other two groups were slightly different in the two scales. In the SEDM scale, those with T1DM between one to three years scored the lowest self-efficacy at all three stage. However, the adherence scores were similar between those diagnosed between one to three years and those with diagnosis more than three years.

Participants in middle school scored the highest adherence, which followed by those in primary school, then by those in the college/university. Participants in high school gave the lowest adherence scores. The results were generally congruent with the result of self-efficacy in the SEDM.

8.2.6. Narrative analysis of webpage usability among participants in subgroups

In “Post-test”, nine participants completed the System Usability Scale (SUS) with a mean score of 79.19 which is deemed as “Good”. This increased to 88.75 (“Excellent”) among six participants in “Retest”. Subgroup review was also conducted as shown in Table 8.7.

Table 8.7. Results of the System Usability Scale (SUS) in subgroups

Items	Subitems	Part 3 "Post-test"			Part 4 "Retest"			Comparison between stages (Part 3-4)
		N	Mean (0-100)	Comparison among subgroups	*N*	Mean (0-100)	Comparison among subgroups	
Gender	Female	5	81.5	Higher	3	89.33	Higher	Increase
	Male	4	76.25	Lower	3	88.83	Slightly Lower	Increase
Age group	10~12 years	1	85		1	80	Increase	Decrease
	13~15 years	2	71.25	The highest	2	82.5		Increase
	16~19 years	6	80.93		3	96		Increase
Diabetes duration	<1year	3	69.17		2	82.5	Increase	Increase
	1~3 years	4	81.67	Increase	2	86.5		Increase
	>3 years	2	87.5		2	97.5		Increase
Education status	Primary school	1	85	The highest	1	80		Decrease
	Middle school	2	71.25		2	82.5		Increase
	High school	4	80.63	Increase	2	96.5	Increase	Increase
	College/University	2	81.25		1	95		Increase

(1) Narratives of changes of webpage usability between stages (Part 3-4)

From "Post-test" to "Retest", participants in most subgroups gave increased scores to the webpages except one participant (A2, a girl who was 12 years in primary school and diagnosed for 18 months). However, both scores of 85 she gave in "Post-test" and 80 in "Retest" indicated the webpages were assessed as "good" (72.75-85.58), which means no real detrimental decrease.

(2) Narratives of changes of webpage usability among subgroups

Female participants assessed usability of the webpages with slightly higher than males in both "Post-test" and "Retest". However, the webpages were assessed to be "Good" by both female and male participants in the "Post-test", which were also assessed as

"Excellent" by both females and males in the "Retest". Therefore, there was no actual gender difference in the assessment of webpage usability in this study.

Results in age groups were slightly different between "Post-test" and "Retest". Scores increased as age group increased in "Retest", which meant those in the 16-19 age group gave the highest usability score. However, in "Post-test", one participant (A2) in the 10-12 age group gave the highest score, which was followed by those in the 16-19 age group. This needs to be interpreted with caution because there was only one participant in the 10-12 age group.

The longer participants had been diagnosed, the higher the scores participants gave to the webpages. In both "Post-test" and "Retest", participants who had been diagnosed more than three years scored the highest on webpage usability. Those with diagnoses less than one year gave the lowest scores on webpage usability; however, they gave the highest self-efficacy in the SEDM scale and the highest adherence in the SCI scale throughout the study.

In "Post-test", a participant (A2) in primary school gave the highest score, and the scores continuously increased from those in middle school to the college/university. However, in "Retest", the webpage usability was generally scored higher when education levels became higher. Although those in high school gave a slightly higher mean score of 96.5 than 95 among those in college/university, both of the two scores meant the same rating of "Excellent" (85.58-99).

8.3. Section 3: Narrative analysis of the scales among participants at item level

In this section, the mean scores of every item of the four scales were calculated at each stage. This is presented in figures or tables to explore whether there were differences in response of the items in a certain scale, including the highest scores participants gave, the lowest, and any large increase or decrease from "Pretest" in Part one to "Retest" in Part four.

8.3.1. Narrative analysis of the Type 1 Diabetes Knowledge scale at item level

Correct answer rates of every item in the Type 1 Diabetes Knowledge (T1DK) scale ranged from 30% on Q4 (The time range HbA1c tests) in "Post-test" to 100% on another five items (Q1-2, Q5-6, Q10). It meant only three out of ten (30%) participants answered Q4 correctly in "Post-test". All participants (100%) gave the correct answers on the five items (Q1~2, Q5~6, Q10) at certain stages. However, only Q5 was answered correctly by all the participants at all three stages.

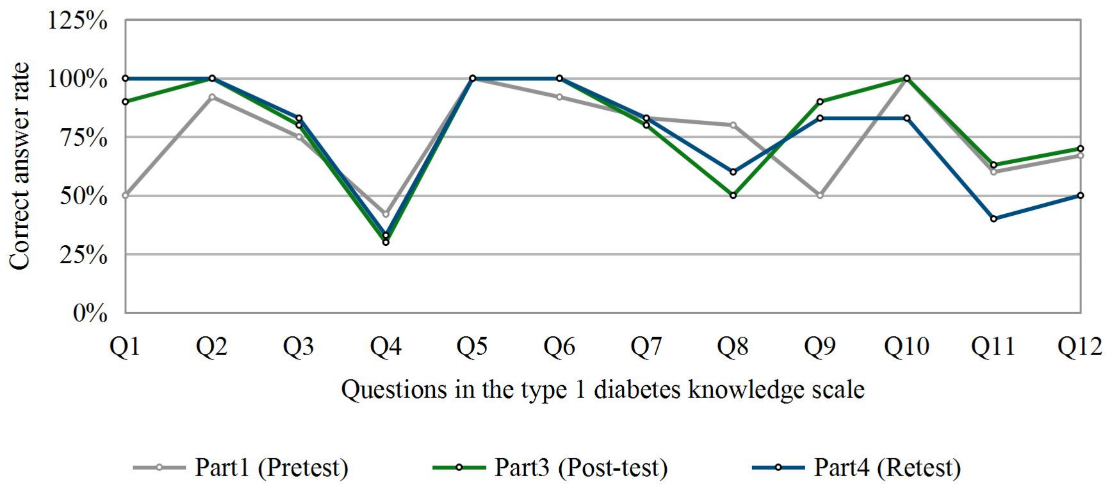


Fig 8.5. Correct answer rates of every item in the Type 1 Diabetes Knowledge scale

(1) The items with the highest and lowest correct answer rates at three stages

As shown in Figure 8.5, four out of 12 items were answered correctly by all the participants (100%) at two or three stages, which were at the peak in Figure 9.4. The items are Q2 (If T1DM can be cured), Q5 (What is diabetes diet), Q6 (What is the recommended exercise frequency) and Q10 (How to deal with low blood sugar). The lowest (Trough) correct rates were on Q4 (The time range HbA1c tests) at three stages, which ranged from 30% in "Post-test" to 42% in "Retest".

(2) The items with the smallest and greatest change from Part one to Part four

In addition to Q5, the correct rates of Q7 (Reasons to test blood sugar) changed slightly between stages. Specifically, ten out of 12 (10/12, 83%) participants gave the right answer on Q7 in “Pretest”, which decreased to 80% (8/10) in “Post-test”, then increasing to 83% (5/6) in “Retest”. However, the correct rates of Q7 were still no less than 80% at all three stages.

The greatest increase of correct answer rates was on Q1 (What is T1DM) between stages, which followed by Q9 (How to Manage T1DM when ill). Specifically, six out of 12 (6/12, 50%) participants gave the right answer to Q1 in “Pretest”, which increased to 90% (9/10) in “Post-test”, then continually increasing to 100% (6/6) in “Retest”. In addition, Q9 was answered correctly among six out of 12 (6/12, 50%) participants in “Pretest”, which increased to 90% (9/10) in “Post-test”, although there was a slightly decrease to 83% (5/6) in “Retest”.

The correct rates reducing with the most between Part one to Part four were Q8 (Insulin storage and injection), which followed by Q11 (symptoms, causes of DKA, and how to deal with) and Q12 (Diabetes check-up). This was not what was expected in this study. However, the correct rates of Q8 reduced from 80% (8 out of 10 participants, 8/10) in “Pretest” to 50% (4/8) in “Post-test”, although there was a slight increase of 10% to 60% (3/5) in “Retest”. The correct answer rates also reduced by 20% on Q11 and decreased by 17% on Q12 from Part one to Part four.

8.3.2. Narrative analysis of the Self-Efficacy in Diabetes Management at item level

Mean scores of every item in the Self-Efficacy in Diabetes Management (SEDM) scale ranged from 6 on Q4 (Adjusting insulin or food based on exercise) and Q6 (Blood sugar checks when busy) in “Pretest” to 8.83 on Q4 and Q10 (Identify difficulties of managing diabetes) in “Retest”.

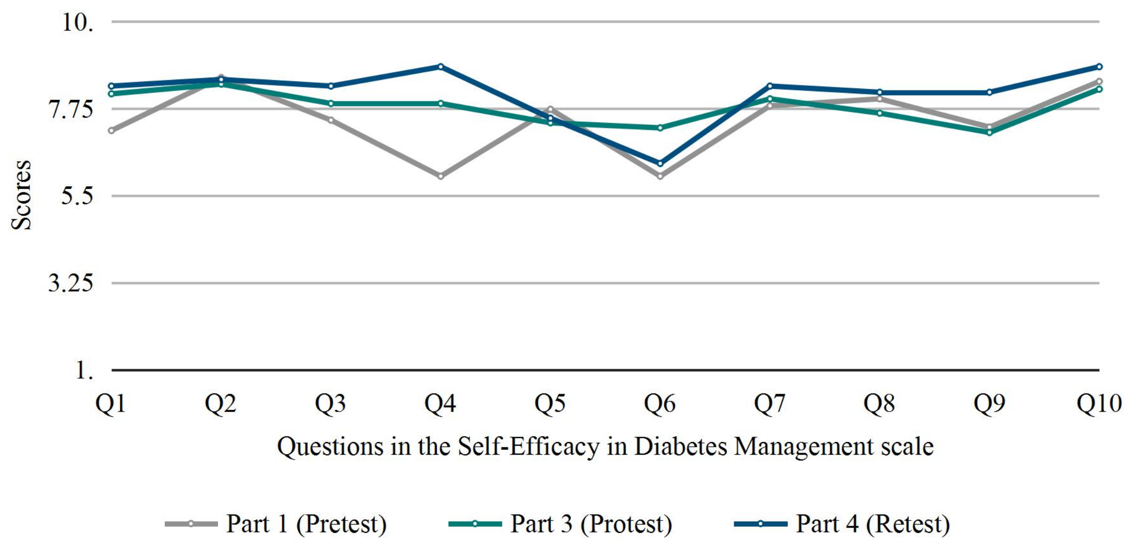


Fig 8.6. The mean scores of each item in the Self-Efficacy in Diabetes Management scale

(1) The items with the highest and lowest scores at three stages

As shown in Figure 8.6, the highest score was given on Q4 (Adjusting insulin or food based on exercise) in “Retest”, which followed by Q10 (Identify difficulties of managing diabetes). Different from Q10 with steady mean scores at three stages, Q4 was also given the lowest scores in “Pretest”, followed by Q6 (Blood sugar checks when busy) in “Pretest”.

(2) The items with the smallest and greatest change from Part one to Part four

The mean scores of Q2 (Choose healthful foods when eating outside) and Q8 (Manage diabetes even when busy) changed slightly from “Pretest” to “Retest”. Specifically, the mean score of Q2 among 12 participants was 8.55 (*SD* 2.16), which reduced to 8.38 (*SD* 1.69) among nine participants in “Post-test” and increased to 8.50 (*SD* 1.05) among six participants in "Retest". In addition, the mean of Q8 also decreased by 0.37 to 7.63 (*SD* 2.00) in "Post-test", then increasing by 0.54 to 8.17 (*SD* 1.33) in "Retest".

The greatest increase of the scores in the SEDM scale was on Q4 (Adjusting insulin or food based on exercise), which was followed by Q1 (Adjust insulin correctly based on eating). As mentioned, Q4 was scored the lowest on self-efficacy at 6.00 (*SD* 3.22) in "Pretest" but was given the highest scores of 8.83 (*SD* 0.75) in "Retest". In terms of Q1, the mean increased by 0.95 from "Pretest" to "Post-test", continuously increasing by 0.2 to 8.33 (*SD* 1.37) in "Retest".

The mean scores only decreased slightly on two out of the ten items in the SEDM scale, including Q2 (Choose healthful foods when eating outside) and Q5 (Talking with doctor or nurse about diabetes management problem). As described about Q2 above, the mean of Q5 also decreased by 0.35 to 7.38 (*SD* 2.33) in "Post-test", then increased by 0.12 to 7.50 (*SD* 2.26) in "Retest".

8.3.3. Narrative analysis of the Self-Care Inventory scale at item level

Mean scores of each item in the Self-Care Inventory (SCI) scale ranged from 1.38 (*SD* 1.06) on Q12 (Warning a medical alert ID) in "Post-test" to 4.83 (*SD* 0.41) on Q5 (Administering insulin at right time) in "Retest".

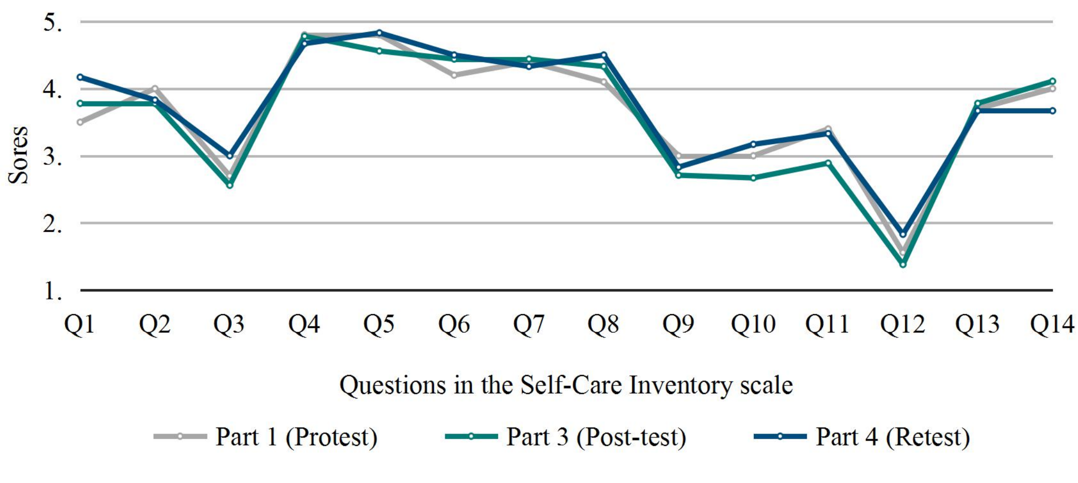


Fig 8.7. The mean scores of each item in the Self-Care Inventory scale

(1) The items with the highest and lowest scores at three stages

As shown in Figure 8.7, five items were given high scores with the means of more than 4.00 at all three stages; Q4 (Administering correct insulin dose), Q5 (Administering insulin at right time), Q6 (Adjusting insulin based on blood glucose value), Q7 (Eating proper food), Q8 (Eating meals on time).

The lowest scores were given on Q12 (Wearing a medical alert ID), followed by Q3 (Ketone testing) and Q9 (Eating regular snacks). Q12 and Q3 were assessed as “not applicable” by participant A12 and A10, separately. Q9 was assessed as “not applicable” by A3 and A5.

(2) The items with the smallest and greatest change from Part one to Part four

The smallest change of the mean scores was found on Q13 (Exercising regularly), which was followed by Q7 (Eating proper food) from “Pretest” to “Retest”. Specifically, the mean score of Q13 among 10 participants was 3.70 (*SD* 0.95) in “Pretest”, which increased to 3.78 (*SD* 1.20) among nine participants in “Post-test” and reduced to 3.67 (*SD* 1.30) among six participants in “Retest”. In addition, the mean of Q7 slightly increased by 0.04 from “Pretest” to “Post-test”, then reduced by 0.11 in “Retest”. However, the means of Q7 were more than 4.0 at all three stages.

The greatest increase in scores was seen on Q1 (Glucose testing). In Part one, Q1 was given a mean of 3.50 (*SD* 0.71), which increased to 3.78 (*SD* 1.20) in “Post-test” and 4.17 (*SD* 0.98) in “Retest”. However, the greatest score decrease was on Q14 (Exercising with great effort). Specifically, the mean of Q14 reduced by 0.44 to 3.67 (*SD* 0.82) in “Retest”, compared with “Post-test”, although a slight mean increase of 0.11 from “Pretest” to “Post-test”.

8.3.4. Narrative analysis of the System Usability Scale (SUS) scale at item level

In the System Usability Scale (SUS), there are five positive statements (items), in which higher scores meant higher assessment of webpage usability, and another five negative statements, in which higher scores meant lower assessment of usability. The SUS scale was assessed only at two stages, “Post-test” and “Retest”. The mean scores of each item are summarised in Table 8.8.

Table 8.8. The mean scores (1-5) of individual items in the System Usability Scale

Modules	Positive statements					Negative statements				
	Q1	**Q3**	**Q5**	**Q7**	**Q9**	**Q2**	**Q4**	**Q6**	**Q8**	**Q10**
Part3 (Protest) (n=9)	4.22±0.83	4.56±0.53	4.22±0.83	4.89±0.33	4.22±0.83	1.44±0.53	1.44±0.88	2.11±1.36	1.67±0.71	4.33±1.00
Part4 (Retest) (n=6)	4.83±0.41	4.83±0.41	4.50±0.84	4.50±0.55	4.67±0.52	1.17±0.41	1.33±0.82	1.33±0.82	1.50±0.84	2.50±1.38
Change of scores	↑	↑	↑	↓	↑	↓	↓	↓	↓	↓
Assessment of usability	↑	↑	↑	↓	↑	↑	↑	↑	↑	↑

Note: Green arrows indicate increase of scores or assessment of webpages usability; Red arrows indicate decrease;

Among the five positive statements, the mean scores among participants ranged from 4.22 to 4.89 at two stages. The mean scores increased on all five positive statements except Q7. Although Q7 (I thought most people would learn to use these webpages very quickly) was given the highest score of 4.89 (*SD* 0.33) in “Post-test”, the mean reduced by 0.39 to 4.50 (*SD* 0.55) in “Retest”.

Among the five negative statements, the mean scores decreased on all the five items, which meant a higher assessment of system usability on each item. Therefore, Q10 (I needed to learn lots of things before I could use this webpages) was given the highest increase in system usability among the five negative statements. However, the mean score of 4.33 (*SD* 1.00) was given on Q10 in "Post-test", which was far higher than another four negative items. This meant a much lower assessment of the system usability on Q10.

8.4. Section 4: A summary of bullet points of the results in the feasibility study

Under the context of the feasibility study with a small sample size, diabetes knowledge, self-efficacy and adherence increased after studying the educational material on the webpages, and the webpage was rated favourably. However, recruitment and completion rates were lower than expected. The results are summarised in Table 8.9.

Table 8.9. A summary of bullet points of the results in the feasibility study

Items	Results and details	
Demographic characteristics and completion status	• Recruitment was lower than expected.	• 16 adolescents registered on the webpages from June 2019 to August 2019;
	• Completion rates at four stages were lower than expected.	• 62.5% (N=10) in "Pretest"; • 62.5% (N=10) in "Education"; • 50.0% (N=8) in "Post-test"; • 37.5% (N=6) in "Retest";
	• The completion rate was lower than expected.	• Six participants completed fully.
	• Imbalanced gender and age group distribution during follow-up;	• Males and younger adolescents (10-15 years) appeared more likely to complete the study;
Scale levels	• Diabetes knowledge, self-efficacy and adherence increased after studying the educational material on the webpages;	• Diabetes knowledge scores (0-100%): • The mean of 75.14% in "Pretest", • 80.33% in "Post-test"; • 76.95% in "Retest";
		• Self-efficacy scores (0-10): • The mean of 7.45 in "Pretest"; • 7.79 in "Post-test"; • 8.13 in "Retest";
		• Adherence scores (0-5): • The mean of 3.68 in "Pretest"; • 3.63 in "Post-test"; • 3.74 in "Retest";
Subgroup analysis	• There were some associations with age, gender and diabetes duration.	• Diabetes knowledge increased as the age group increased. The lowest Diabetes knowledge was among those with a diagnosis of 1-3 years, and highest in those with a diagnosis of more than 3 years.
		• Males, those in the 13-15 age group or with a diagnosis of less than one year scored with the highest self-efficacy.
		• Males, those in the 13-15 age group or with a diagnosis of less than one year scored with the highest adherence.
Item levels	• In the type 1 diabetes knowledge (T1DK) scale, a ceiling effect needs to be retested on certain items (Q1-2, Q5-6, Q10) in future.	
Webpage usability	• The webpage was rated favourably.	• Webpage usability scores (0-100): • The mean of 79.19 ("Good") in "Post-test"; • 88.75 ("Excellent") in "Retest";
	• Females, those in older age group, or had higher formal education level, or had been diagnosed longer preferred to give a better assessment.	

CHAPTER 9 DISCUSSION AND CONCLUSION

In this chapter, the results of the feasibility study are discussed in following six sections:

1) Problems met during participant recruitment and follow up;

2) Changes of diabetes knowledge among participants after studying the web-based type 1 diabetes educational material in Part two "Education";

3) Changes of self-efficacy after learning the web-based material;

4) Changes of adherence after learning the web-based material;

5) Participants' assessment on webpage usability;

6) Feasibility and limitation of the study;

.7) Conclusion of the feasibility study.

9.1. Participants recruitment and follow-up

9.1.1. Recruitment of participants

(1) Lower recruitment rate

In this feasibility study, 85 participants who were 10-19 years and had been diagnosed with T1DM were screened from the information system of a university hospital in China. However, only 32 (38%) eligible adolescents and their parents consented to take part in the study through phone calls. This seemed to be relatively higher than that in some studies (Hinojosa et al., 2014, Quirk et al., 2018). About 32% of eligible children (9-11 years) with T1DM and their parents gave a consent to participate in a physical activity intervention in a randomised feasibility trial (Quirk et al., 2018). Another study reported 15.8% of eligible adolescents (14-18years) who were low income, racially and ethnically diverse agreed through phone calls to participate and 7.3% signed the consented forms in a focus group study (Hinojosa et al., 2014). Finally, 16 adolescents registered on the webpages in this study. The recruitment rate was 19% (16/85) in the feasibility study, and lower than 25%-40%, which was considered to be reasonable (Quirk et al., 2018). Reasons of lower recruitment rate were mainly explored under four kinds of factors: participant-; cultural-; study-; and organisation-related factors.

First, participants played a major role in the low recruitment rate. In this feasibility, 16 (19%) potential participants had changed their phone numbers and were excluded. In China, phone number changes have been common in recent years because of fierce business competition between three major mobile communication operators in China (Zhou et al., 2017). The customer attrition rate (mobile phone number changing) varied between cities and operators (Hua, 2011, Du, 2013, Liu, 2016, Zhou et al., 2017). In Beijing, more than 560,000 to 860,000 clients of Mobile China (one of the three major operators) were reported to give up their mobile phone numbers each month in January 2015 to November 2015 (Liu, 2016). Around 50% of lost customers were those with low spending (less than 50 or 80 RMB) who were more easily affected by sales promotion (Du, 2013, Liu, 2016). This may be related to unavailability of mobile number portability (MNP) in China, which only began to be tested in November 2019 according to the Ministry of Industry and Information Technology (MIIT, 2019). MNP means customers can retain their phone number when switching operators, which has been implemented in many countries like Singapore and the United Kingdom (Singh and Sirohi, 2015). In addition, another 17 (20%) potential participants were excluded mainly because of three other reasons, including refusing or missing the calls, or their phone being switched off. This result was different from what was expected in this study because a phone call was reported to be an effective method to recruit participants in some clinical trials in other countries (Duncan et al., 2004, Heerman et al., 2017), as well as the popularity of mobile phones in China. Furthermore, the lower recruitment rate would be also related to three other factors mentioned as below.

Second, in terms of cultural factors, interpersonal mistrust in Chinese culture (Yao et al., 2017) would be an important cultural barrier to recruiting participants in this study. This could be affected by Confucian social ethics with only emphasis on ritual and civility in concrete personal relationships, rather than in any interpersonal dealings beyond the face-to-face level (Steinhardt, 2011). Chinese people unconditionally trust their own family members (the core "in-group"), but distrust others who are not part of one's family ("out-group") (Feng et al., 2016). This kind of mistrust existed between parents and me throughout the recruitment process. Although I am a nurse at the hospital, I was a stranger to the parents because I was not their children' charge nurse when hospitalised and in any case many adolescents were only outpatients who had no charge nurses. The mistrust can be seen in a parent's complaint about fraudulent messages from me, which caused termination of text message function of my phone number. Afterwards, potential participants were called from a fixed-line telephone in the hospital (the Affiliated Hospital of Southwest Medical University), which was directly tied to a geographical location connecting to the hospital and always began with the same eight numbers (0830-3165***). Many parents still questioned directly or indirectly my status as a nurse during the phone calls. This may be because fraudulent phone calls have been rampant in China (Peng and Lin, 2018). However, a meta-synthesis reported that mistrust was also a prominent barrier to recruit patients among Chinese immigrants in clinical trials (Limkakeng et al., 2013).

Third, a phone call was considered a good way to recruit participants when the feasibility study was designed. However, the lower recruitment rate indicated the recruitment strategies should be improved in a future trial. According to a comparative descriptive study in Canada, pharmacies were considered to be the most effective method (38% of recruitment rate) to recruit participants with chronic disease, followed by paper mail (34%), word of mouth (12%) and media (8.7%) (Kakumanu et al., 2019). In another study in Oxford (UK), among ten recruitment strategies, web-based advertising (22.3%) recruited the highest number of participants with a history of recurrent depression, followed by poster advertising (19.6%), radio advertising (17%), general practitioner (GP) (11.8%) and word of mouth (10.5%) (Krusche et al., 2014). In China, roughly 70% of patients indicated their doctors' mention or recommendation was likely to affect their decision to take part in a study (Wu et al., 2015). In addition, monetary or material incentives were also assessed to be effective methods to improve the recruitment rate (Mapstone et al., 2007).

Fourth, the organisation (hospital) also contributed to the lower recruitment rate. In the electronic medical record (EMR) system of the hospital, 13 potential participants were recorded without phone numbers and excluded in this study. This may be because a phone number had been not required for doctors to complete in the old EMR system, however, this problem had been solved in the new EMR system.

(2) Imbalanced gender and age group distributions during recruitment

In addition to low recruitment rate, imbalanced gender and age group distributions were also found among participants who registered on the webpages in the feasibility study. Specifically, among 16 participants registered on the webpages, 11 (69%) were female. To try to analyse reasons for the imbalance, the original data from 85 potential participants was reviewed. Among 85 potential participants who were 10-19 years with T1DM, 55 (65%) of them were females, which was similar to the percentage (69%) of female participants who registered on the webpages. In addition, the result of age group distribution was also similar. Among 85 potential participants, 11 (13%) of them were in the 10-12-age group, and 47 (55%) were in the 16-19-age group. The proportions at different age groups were also consistent with that of the participants who registered on the webpages. Specifically, two (13%) of 16 participants were in the 10-12-age group and nine (56%) were in the 16-19-age group. The analysis indicated that the imbalanced gender and age group distributions among participants who registered on the webpages in this study may be caused by imbalanced distributions of population with T1DM in Luzhou (a city of southwest of China) and perimeter.

Although there was no reliable data about incidence of children and adolescents with T1DM in Luzhou and perimeter (southwest of China), the results from 14 Chinese medical centres also showed a slightly higher incidence of T1DM in girls than boys who were aged 0-18 years (Fu et al., 2013). Another study in Zhejiang province (southeast coast of China) also reported a higher risk of T1DM in girls (0-19 years) than in boys (Wu et al., 2016). However, the overall sex ratio was roughly equivalent among children (<15 years) with T1DM in Europe and Africa (Motala et al., 2003, Kyvik et al., 2004, Soltesz et al., 2007). In the 15 to 19-year group, the incidence of T1DM was estimated to be higher in males than in females in most European centres, including Leicestershire and West Yorkshire in the UK (Kyvik et al., 2004), and Sweden (Ostman et al., 2008). In addition to gender difference of T1DM incidence, females were also reported to be more likely to be influenced by friends, family or researchers to participate in a clinical trial (Lobato1 et al., 2014).

9.1.2. Follow-up of participants

(1) Low completion rate

The completion rates of the webpages reduced from 62.5% in Part one "Pretest" to 37.5% in Part four "Retest". The full completion rate was 37.5% (6/16) in this study. A review reported excellent retention of 74% to 100% in adolescents with diabetes during follow-up visits of clinic trials by offering compensation to patients (Nguyen et al., 2014). In a feasibility study of physical activity intervention for children (9-11 years) with T1DM, the retention rate was 77% at the 3-month follow-up. However, only 13 participants were recruited to attend this feasibility (Quirk et al., 2018). It was recommended a retention rate of at least 70% should be acceptable at each time point of clinic trials (Blake et al., 2016).

Both participants and research design may contribute to the low completion rates in this study. A global survey from 68 countries indicated that participating in clinical trials was perceived as inconvenient and burdensome, and around 50% respondents expressed that clinical trial disrupted their daily routine (Anderson et al., 2018). In comparison with patients from USA, those from China cared more about the likelihood of self-benefit. Receiving free medical care and financial incentives had greater effect on their participation and retention (Wu et al., 2015). In any future trial, participants can also be interviewed to explore their suggestions to improve completion rates, with ethical permission.

In terms of study design, establishing a sense of trust with adolescents and their guardians is crucial for successful clinical trials (Nguyen et al., 2014). Being able to contact clinicians directly for advice was emphasised by parents to gain the sense of trust, however, peer support was considered to be more helpful by children in a quantitative research (Farrington et al., 2016). Continuous and regular contact between patients, parents and research staff was also mentioned in some studies (Blanton et al., 2006, Yancey et al., 2006, Nguyen et al., 2014). A systematic review presented that incentives were associated with an increase of overall retention rates in ten studies (Booker et al., 2011). Incentives include monetary incentives, material incentives, such as film gift certificates and retail store gift voucher, technology-based incentives, such as prepaid mobile phones, and others, like the possibility of new relationships with peers with the same diagnosis (Jones and Broome, 2001, Mapstone et al., 2007, Nguyen et al., 2014).

(2) Imbalanced gender and age group distributions during follow-up

In addition, males were more likely to complete the study because 60% (3/5) of male participants fully completed the study, and only 27% (3/11) of females fully completed it. This was similar to another study in USA, which tested the feasibility of conducting a personalised exercise intervention among adolescents (12-19 years) with T1DM (Faulkner et al., 2010). The results showed that 69% (9/13) of male participants fully completed the 16-week exercise programme, however, only 27% (3/11) of females fully completed (Faulkner et al., 2010). In this study, participants in the 16-19-year age group were more likely to lose to follow up than others in the 10-12- and 13-15-year age groups. Another study about HIV-prevention intervention among adolescents also presented similar result. Older girls (*Mean* age of 17.09 years) were less likely to attend sessions than younger girls (*Mean* 16.50) in the study (Seibold-Simpson and Morrison-Beedy, 2010). However, the sample size was limited, and the feasibility study was only conducted in a hospital. The results cannot be interpreted except for a confirmation in a future trial with a big enough sample size.

9.2. Changes of diabetes knowledge among participants

In this study, web-based type 1 diabetes educational material was developed specifically for adolescents (10-19 years) with T1DM. To assess whether the web-based material could help participants improve their diabetes knowledge, the type 1 diabetes knowledge (T1DK) scale was developed because there were no scales found to be appropriate for this study. During the proposal designing, psychometric properties were designed to be test if the T1DK scale was reliable and valid. However, owing to a small sample size, only readability and content validity were evaluated in the feasibility study.

In this section, change of diabetes knowledge before and after learning the web-based diabetes material will be explained at scale and item levels, rather than testing the preliminary effect of web-based material on diabetes knowledge through T-test. However, the results also needed to be interpreted with caution because of the small sample size in this feasibility study.

9.2.1. Changes of diabetes knowledge at scale level

(1) Overall trend of change in diabetes knowledge

The mean correct answer rate of diabetes knowledge was 75.14% (42-100%) in Part one "Pretest" in this study, which was similar to the results of another two studies (O'Neil et al., 2005, Mangla et al., 2019). A study in southeast United States indicated a correct response of 72% among adolescents (9-17years) with T1DM by using a modified version of the Diabetes Knowledge Test (O'Neil et al., 2005). Another study in India showed a mean correct answer rate of 63.7% among adolescents and young adults with T1DM at the age of 3-26 years through a 34-item Diabetes Knowledge Test (DKT) scale (Mangla et al., 2019). Another study only reported the correct answer rates ranged from 51% to 95% between items of the Mercy What I Know About Diabetes (M-WIKAD) among adolescents (12-18 years) with T1DM, however, an average correct rate was not presented (Tsai et al., 2019).

In this study, the correct answer rate increased by 1.59% to 80.33% in Part three "Post-test", which was consistent with the purpose of this study to improve diabetes knowledge among adolescents. The increase would be mainly related to the web-based type 1 diabetes educational material. Specifically, nine of ten participants got the same or increased scores in "Post-test". Only one participant (A2) who was a 12-year girl got decreased scores from 75% in "Pre-test" to 50% in "Post-test". Three items of the T1DK scale were answered correctly by her in "Pretest" but answered incorrectly in

“Post-test”, including typical symptoms of type 1 diabetes, insulin storage and injection and diabetes check-up. The three aspects of contents were mentioned in the web-based material. The decrease may be related to limited learning and understanding ability because the participant was studying in the primary school.

“Retest” measures the stability of the responses from the same participants. Compared with “Post-test” (80.33%), the correct rate decreased to 76.95% in Part four “Retest” two weeks later. Another two studies tested validation of the Mercy What I Know About Diabetes (M-WIKAD) (Tsai et al., 2019) and the diabetes knowledge test (DKT) (Mangla et al., 2019) among children and adolescents with T1DM. No data were reported about test-retest reliability. However, an American study (Quandt et al., 2014) included 593 participants for the initial test, and 46 of them were invited to finish the Short Diabetes Knowledge Instrument (SDKI) again a month later. The mean knowledge scores were reported to increase slightly at the repeated test. However, participants in this USA study were older adults (≥60 years) with diabetes (Quandt et al., 2014). In this study, the mean correct rate in “Retest” (76.95%) was still higher than that in Part one “Pretest” (75.14%). Considering participants’ characteristics, the scores decreasing in “Retest” may be because of incomplete understanding of some details in the material or forgetting some contents over time according to forgetting curve theory (Averell and Heathcote, 2011), which showed memory sharply dropped within the first few days after learning without review. The reasons can be explored further through a qualitative study in future. The long-term effect or replicated interventions could also be considered in a future trial.

(2) Findings and discussion in subgroup results

Gender was found to have no relationship with diabetes knowledge among adolescents (10-19 years) with T1DM in this study, which was consistent with the results of other studies (O'Neil et al., 2005, Flora and Gameiro, 2016, Mangla et al., 2019, Tsai et al., 2019) among children and adolescents with T1DM. Two studies in the USA reported no significant difference between females and males in diabetes knowledge by using two different scales. The modified Diabetes Knowledge Test (DKT) was selected to test knowledge among adolescents aged 9 to 17 years (O'Neil et al., 2005) and the Mercy What I Know About Diabetes (M-WIKAD) scale was developed for adolescents at the age of 12-18 years with T1DM (Tsai et al., 2019). A cross-sectional study among 51 adolescents (12-18 years) with T1DM in Portugal also reported that there was no relationship between gender and diabetes knowledge, in which a self-developed diabetes knowledge scale was used (Flora and Gameiro, 2016). A 34-item diabetes knowledge test (DKT) scale in Hindi language was created for young Indians (3-25 years) with T1DM, and no association was found in diabetes knowledge among females and males (Mangla et al., 2019). However, the result needs to be interpreted with caution because sample size was limited in this feasibility study.

Correct answer rates of diabetes knowledge through the T1DK scale increased as the age group (10-12; 13-15; 16-19 age group) in this study, which was similar to the results of another five studies (Du Pasquier-Fediaevsky et al., 2002, O'Neil et al., 2005, Flora and Gameiro, 2016, Keller et al., 2017, Tsai et al., 2019). Except the three studies mentioned above (O'Neil et al., 2005, Flora and Gameiro, 2016, Tsai et al., 2019), two French studies also demonstrated that age was positively correlated with diabetes knowledge by using the diabetes knowledge and skills (DKS) (Keller et al., 2017) and the Test of Diabetes Knowledge (TDK) scale (Du Pasquier-Fediaevsky et al., 2002). This may be interpreted by increasing intellectual development, self-learning ability and understanding ability as adolescents' age increased.

Nevertheless, this seems to be contradictory with the result about education level because participants in the university group did not get the highest scores in this study.

This should be interpreted with cautions because only two participants were included in the university group. No other study was found discussing the relationship between education levels and diabetes knowledge among children or adolescents with T1DM. However, diabetes knowledge was reported to be associated with the level of maternal education, that is, children with higher maternal education (>class12th) got better scores than those with lower maternal education (≤class12th) (Mangla et al., 2019). Several studies reported positive relationship between education level and diabetes diagnosis knowledge among adults with diabetes (Fitzgerald et al., 1998, Collins et al., 2011, Bukhsh et al., 2017). In 1998, a 23-item brief Diabetes Knowledge Test (DKT) scale was developed for adults, and the result showed diabetes knowledge significantly increased as the years of formal education completed increased among adults (Fitzgerald et al., 1998). This was congruent with another study, in which a 24-item Urdu version of Diabetes Knowledge Questionnaire (DKQ) was examined in Pakistan (Bukhsh et al., 2017). In 2014, the DKT scale was revised with several modified words (DKT2), and participants with high school graduation or less were found to have significantly lower scores than those who went to college or university (Fitzgerald et al., 2016).

A relationship was also indicated between knowledge and diabetes duration in this study. Participants who had been diagnosed with T1DM more than three years got the highest correct answer rate. However, those who had been diagnosed with one to three years got the lowest correct answer rate, which seemed to be different from what was expected. However, this result was also consistent with the result in the Self-Efficacy in Diabetes Management (SEDM) scale. Participants who had been diagnosed with one to three years scored the lowest self-efficacy in the SEDM scale. This could be recognised as a plateau period for adolescents because diabetes management is a long-term and challenging chronic condition. Optimal blood glucose, insisting on diabetes regimen and relationship with families and friends are difficult for adolescents to sustain all the time (King et al., 2017). However, the results should be interpreted with caution because of small sample size in this study. The relationship between diabetes knowledge and adolescents' characteristics, such as age, gender, diabetes duration and education level, should be re-tested in the future trial with further explanation about underlying reasons.

9.2.2. Changes of diabetes knowledge at item level

(1) The item with the lowest correct answer rate

In the 12-item T1DK scale developed in this study, Q4 "The time range HbA1c tests" was answered with the lowest correct answer rates, which were less than 50% at all three stages. This result was similar to another study among adults in the USA (Fitzgerald et al., 1998), in which the same question was included in the Diabetes Knowledge Test (DKT) scale. It was reported that only 29% participants answered the item (item#5) correctly in the DKT scale (Fitzgerald et al., 1998). Furthermore, the revised DKT2 scale was tested again in 2014-2015 (Fitzgerald et al., 2016). Although increasing to 66%, correct answer rate of this item (item#5) was only higher than two out of 23 items in the DKT2 scale (Fitzgerald et al., 2016). In another study with the Simplified Diabetes Knowledge Scale (RDKS), only 33% participants in the UK answered this question (item#2) correctly (Collins et al., 2011). This may be because this item is not related to daily diabetes management and easy to be ignored by patients and diabetes educators.

(2) The item with the highest correct answer rate

Four items were answered correctly by all the participants (100%) at two or three stages, Q2 "If T1DM can be cured", Q5 "What is diabetes diet", Q6 "What is the recommended exercise frequency" and Q10 "How to deal with low blood sugar". This is referred to as a "ceiling effect" in statistics. If more than 15% of respondents achieved the highest possible score, participants cannot be distinguished from each other and changes cannot be measured among participants (Terwee et al., 2007). Thus, reliability of the scale would be reduced. However, only two out of 12 items in this study were answered correctly by 100% participants before learning the web-based material in "Pretest". In addition, this was only a feasibility study with a small sample size. The ceiling effect needs to be considered and tested again in a future trial.

(3) Items with slight or marked changes

The correct answer rate of the item Q7 "Reasons to test blood sugar" changed slightly between stages, however, the correct rates were still no less than 80% at all three stages. This was because two participants (A2, a 12-year girl in primary school; A11, a 19-year female in the university) incorrectly answered this item at all three stages, and A11 lost to follow up in "Retest". On the item Q7, the two participants chose option B 'To help them make right decision at some special time' as the correct answer. They ignored the importance of blood sugar testing in daily life as option A, which was a common phenomenon in China (Luo et al., 2017, Raoufi et al., 2018). In a multi-centre registry study in China with the involvement of 18,995 patients with type 2 diabetes from 209 hospitals, the mean self-reported frequency of self-monitoring blood glucose was around 5 times a month (Luo et al., 2017). In Shandong Province (part of the East China region), even 51.4% of patients with diabetes tested their blood glucose more than once a month (Raoufi et al., 2018). A systematic review reported a number of reasons for discontinuation of blood sugar testing among patients, such as pain, discomfort, increased anxiety and depression, constant reminder of illness, being seen as a proxy measure for 'good and bad' behaviour, rather than an aid to better diabetes self-management (Clar et al., 2010).

There were two items with marked increase after studying the web-based material, including Q1 “What is T1DM” and Q9 “How to Manage T1DM when ill”. Considering the target population in this study, the educational material simplified the difficult diabetes knowledge by using images and dialogues. However, the correct answer rates reduced on another three items with great rates, Q8 “Insulin storage and injection”, Q11 “symptoms, causes of DKA, and how to deal with” and Q12 “Diabetes check-up”. The three items may be relatively difficult for participants, and incomplete understanding of the material would confuse participants. For example, three out of six participants in “Retest” selected option A “When you have the symptom of vomiting, deep sighing breath, breath smell like rotten apple, or even coma, you may be experiencing DKA” as the false statement of Q11, which should be correct. However, the option B “Maybe DKA can happen to people like you if you inject excess insulin and eat less food” should be ‘false’, which was not identified by the three participants in “Retest”. Maybe repeated learning of the material could be helpful for participants to understand some relatively difficult contents.

9.3. Changes of self-efficacy among participants

The Self-Efficacy in Diabetes Management (SEDM) scale was selected to test self-efficacy among adolescents with T1DM in this study, in which score system ranges from 0 to 10. However, reliability and construct validity of the SEDM scale in Chinese could not be tested because sample size of the feasibility testing study was limited. Therefore, change in self-efficacy before and after studying the web-based diabetes material will be explained at scale and item levels, rather than testing the preliminary effect of web-based material on self-efficacy through T-test. However, the results need to be interpreted with caution because of the small sample size in this feasibility study.

9.3.1. Changes of self-efficacy at scale level

(1) Overall trend of change in self-efficacy

In Part one "Pretest", participants scored a relatively high self-efficacy (a mean of 7.45) through the SEDM scale in this study. This was slightly lower than self-efficacy (a mean of 7.50) given by 168 adolescents aged 10-16 years old with T1DM in an American study (Iannotti et al., 2006), in which the SEDM scale was also selected. However, the mean scores of the SEDM scale in another two American studies (Herge et al., 2012, Hughes et al., 2012) were slightly lower than the result of this study. The mean self-efficacy score was 6.90 among 137 adolescents (10-14 years) in one study (Hughes et al., 2012) and 7.08 among 257 adolescents (11-14 years) in another study (Herge et al., 2012). The participants in the two studies were younger, compared with this study.

The mean self-efficacy score increased slightly in Part three "Post-test", which was consistent with the purpose of this study to improve self-efficacy among adolescents. The increase of self-efficacy would be relevant to the web-based type 1 diabetes educational material developed in this study. Specifically, six of eight participants scored the same or increased self-efficacy in "Post-test" except two girls. A3 was a 17-year girl who especially gave lower scores in "Post-test" to two items (Q9 and Q10) which belong to emotional capacity for diabetes management. Some studies demonstrated that female adolescents had a more negative perception of their disease (Wisting et al., 2016), had significantly higher anxiety, depression and distress (Moussa et al., 2005, Forsander et al., 2017), and used less active coping and more avoiding in psychological adjustment (Enzlin et al., 2002). A8 was a 19-year girl who gave an especially lower score to Q5, which is about talking to a doctor or nurse about any diabetes management problems. Sense of mistrust and deficit in communication between patients and health professionals contributed to this problem in China (Shen et al., 2013), which will be mentioned later.

In Part four “Retest”, self-efficacy continued to increase in this study two weeks later after completing the web-based material. Although the mean correct rate of diabetes knowledge decreased in “Retest”, the mean of self-efficacy increased in “Retest”, as well as adherence. However, it needs to be interpreted with caution because of a small sample size in the feasibility study. Although there was another study in USA (Iannotti et al., 2006) assessing the test-retest reliability of the SEDM scale among adolescents with T1DM, test-retest reliability was reported to be acceptable without specific mean score of self-efficacy (Iannotti et al., 2006).

(2) Findings and discussion in subgroup results

Although females scored higher self-efficacy in the SEDM scale than males in “Pretest” and “Post-test”, males scored higher on self-efficacy than females in “Retest”. Another three studies using the SEDM scale to test self-efficacy among adolescents with T1DM also reported mixed results about the relationship between self-efficacy and gender. A study in the northeastern United State recruited 89 adolescents between the age of 16-19 years, which reported females had higher SEDM scores than males with a statistically significant difference (Wilt, 2019). However, another study recruiting 168 adolescents from 16-19 years at urban university medical centres reported the opposite result, which was that boys had significantly higher SEDM scores in USA (Iannotti et al., 2006). In a Danish study, the SEDM scale was divided into two sub-scales, SEDM1 (Q1-4) which referred to practical diabetes management and SEDM2 (Q5-10) which referred to emotional capacity. The average SEDM2 score was found to be higher in girls than in boys at age 12 and decreased as age increased among girls. From age 12, boys' self-efficacy score in the SEDM2 sub-scale increased and became higher at 17 years old than self-efficacy in girls (Lindkvist et al., 2018).

In this study, adolescents in the 13-15 age group scored the highest self-efficacy, and those in the 16-19 age group scored the lowest. This seems to contradict the results for the diabetes knowledge because participants in the 16-19 age group gave the highest correct answer rate in the T1DK scale. Furthermore, older adolescents were reported to have higher levels of self-efficacy in another study. However, it only included 89 participants at the aged of 10-16 years. Specifically, those in the 13-16 age group were reported to score higher self-efficacy than those in the 10-12-year group although there was no statistical significance (Wilt, 2019), which was actually consistent with this study. The adolescents in the 16-19-year age group scored the lowest self-efficacy in this study. This was congruent with the result of adherence because those in the age of 16-19-year group also scored the lowest adherence in the SCI scale in this study. This may be correlated with worse metabolic control (Rica et al., 2017) and more psychosocial problems among older adolescents (Guthrie et al., 2003).

Those who had been diagnosed with T1DM less than one year scored the highest self-efficacy in the SEDM scale. This may be because they began to accept their diabetes after a short adjustment and learn to manage their own disease (Guthrie et al., 2003). A study from 207 centres in Germany and Austria also reported the best HbA1c levels were achieved in the first two years after diagnosis among adolescents with T1DM (Gerstl et al., 2008). In this study, participants with a diagnosis between one to three years scored the lowest self-efficacy, which was congruent with the result of the diabetes knowledge scale. Those who had been diagnosed between one to three years also had the lowest correct rate in the T1DK scale. The reasons could be explored in a qualitative study in future, and the relationship between diabetes duration and self-efficacy needs to be explored further in a future trial with bigger sample sizes.

Participants in middle school scored the highest self-efficacy, and those in high school gave the lowest scores in the SEDM scale. This seemed to be congruent with the results of the age groups because those in the 13-15 years scored the highest self-efficacy who should also study in the middle school in Chinese education system. Those in high school who should be in the 16-19 age group had the lowest self-efficacy, although they had the highest correct diabetes knowledge scores. As mentioned before, this could be relevant to worse metabolic control and more psychosocial problems among older adolescents. A future trial will be conducted to test the results again because of a small sample size in this feasibility testing study. The relationship between self-efficacy and adolescents' characteristics, such as age, gender, diabetes duration and education level, should be re-tested in the future trial with further explanation about underlying reasons.

9.3.2. Changes of self-efficacy at item level

Compared with other items of the SEDM scale, Q4 "Adjusting insulin or food accurately based on exercise" was given the lowest score in "Pretest". This was similar to the results of a study in northeastern United State (Wilt, 2019), in which Q4 was the third lowest item in the SEDM scale. However, the same study showed that Q1 "Adjust your insulin correctly when you eat more or less than usual?" was given the highest score (8.55) (Wilt, 2019), which was also given relatively high scores (7.18-8.33) in this study. This meant that adolescents believed that they could do some simple work of insulin adjustment by themselves, such as increasing or decreasing insulin dosage according to the amount of food they eat. But when exercise is involved in the insulin regimen, it may be difficult for them to adjust insulin dosage by themselves. Furthermore, in this study, Q4 was also given the highest self-efficacy by participants after reading the web-based educational material, in which importance and some specific principles of insulin treatment and adjustment were addressed.

In this study, after working through the web-based diabetes material, adolescents' self-efficacy decreased slightly on Q2 "Choose healthful foods when eating outside" in the SEDM scale, which was also scored with the lowest scores in an American study (Wilt, 2019). This may be because eating habit is hard to change for people, especially among Chinese people because food is not only the source of nutrition in Chinese society, but also a means to establish and maintain interpersonal relationship (Ma, 2015). Q7 "Eating proper food" in the SCI scale was also given a decreased score in this study. Eating adherence was presented to be one of the most problematic area for adolescents with T1DM worldwide (Eisenberg et al., 2016). Compared with peers, eating problems, including disordered eating behaviour which is a kind of milder eating problems and eating disorders which can be clinically diagnosed, such as anorexia nervosa and bulimia nervosa, were more common in adolescents with T1DM (Young et al., 2013). Environmental, family and other psychosocial factors, such as the role of relatives or peers with diabetes and adolescent development, were reported to make dietary compliance more challenging (Mulvaney et al., 2006, Parker et al., 2013). However, counseling by a Registered Dietician, family food environment or eating at home, and strong parent-child relationship correlated with improved eating behaviours and eating-related attitudes (Parker et al., 2013). A meta-analysis also presented that the frequency of shared family meals was significantly related to eating health in children and adolescents (Hammons and Fiese, 2011).

In the SDEM scale, talking with doctors or nurses about diabetes management problem was scored slightly lower in Part four "Retest" in this study. This is culture-related variance, which may be not only related to adolescents' responsibility, but also to the social circumstance in China. A sense of mistrust between patients and health care practitioners, busy treatment work for doctors and nurses, limited diabetes education sources, lack of standards of practice for diabetes educators and deficit of systematic diabetes education arrangement were identified as barriers for effective diabetes education in China (Wilson and Gyi, 2010, Shen et al., 2013).

9.4. Changes of adherence among participants

The self-care inventory (SCI) scale was selected to test adherence of diabetes management among adolescents in this study, in which the score system ranges from 0 to 5. However, psychometric properties of the SEDM scale in Chinese could not be tested because of limited sample size in the feasibility testing study. Therefore, change of adherence before and after studying the web-based diabetes material will be explained at scale and item levels, rather than testing the preliminary effect of web-based material on adherence by t-test.

9.4.1. Changes of adherence at scale level

(1) Overall trend of change in adherence of diabetes management

In "Pretest", the mean score of adherence in the 14-item Self-Care Inventory (SCI) scale was 3.68 in this study, which was lower than in another study (Hughes et al., 2012). In the American study, the mean adherence score of 3.90 was reported among adolescents (10-14 years) with T1DM through the 16-item SCI scale (Hughes et al., 2012). The 14-item SCI scale was also selected in another American study to assess self-efficacy among adolescents aged 11-18 years, however, the mean score of 36.9 was presented, which was hard to compare with the result of this study because of different computing process (Lewin et al., 2009). A Japanese study reported the mean adherence score of 97.5 among 212 children and adolescents (9-18years) with T1DM from six prefectures in Japan through a revised diabetes self-care inventory (R-DSCI), which included 41 items with the score range of 47-141 (Nakamura et al., 2019).

In this study, the mean of the SCI scale slightly decreased to 3.63 in Part three "Post-test", which was counter intuitive and needed to be verified in a future trial. In Part four "Retest", the scores for adherence increased slightly to 3.74. There was no specific data mentioned for adherence among adolescents with T1DM in another study, although a strong correlation was identified in the test-retest reliability (Lewin et al., 2009). The result of adherence in this study seemed to be congruent with the result of self-efficacy, which continued to increase in "Retest". Self-efficacy was reported to be positively associated with adherence of diabetes management among adolescents with T1DM (Littlefield et al., 1992, Iannotti et al., 2006). However, self-reported adherence is subjective and inaccurate, and objective measures, such as HbA1c or daily blood glucose levels, should be considered in future trials. The result of this study needed to be retested in a future trial.

(2) Findings and discussion in subgroup results

In this study, males scored higher adherence than females through the SCI scale at all three stages, which seemed to be different from the results of another two studies (Alan et al., 1990, Nakamura et al., 2019). There was also no correlation found between gender and total adherence score among children and adolescents with T1DM in Japan, however, the subscale "physical activity" was scored significantly higher by boys than girls (Nakamura et al., 2019). A cohort among children and adolescents (9-16 years) with T1DM in the USA reported that gender was not predictive for adherence of diabetes management, in which adolescents' adherence was judged by pediatric diabetologists at clinic visits (Alan et al., 1990). Nevertheless, yet another American study identified the significant correlation between gender and adherence among 50 adolescents (11-18years) with T1DM through the SCI scale, which presented females were more likely to have higher self-reported adherence in diabetes management (Wooten, 2014).

Adherence was scored higher as age group of participants decreased in this study. Specifically, those in the 13-15 age group scored the highest, and those in the 16-19 age group scored the lowest. The findings of other two studies among children or adolescents with T1DM also indicated that older adolescents were less likely to comply with their diabetes treatment regimens than younger adolescents (Alan et al., 1990, Greening et al., 2007). Another study in Japan also demonstrated that age was negatively correlated with total adherence score through the revised diabetes SCI scale (R-DSCI) among children and adolescents with T1DM, as well as the scores of four subscales, “family support and attitudes towards diabetes self-care” “regularity of snacks and insulin injection”, “blood glucose monitoring” and “physical activity” (Nakamura et al., 2019). A national study in Denmark also presented that lower age was significantly associated with better adherence among 519 adolescents with T1DM between 12-17 years, in which a self-developed scale “Adherence in Diabetes Questionnaire (ADQ)” was used to test adherence (Kristensen et al., 2018).

In this study, those who had been diagnosed with diabetes less than one year scored the highest adherence scores in the SCI scale. The scores in another two sub-groups were similar, including those with diabetes between one to three years and those with diabetes more than three years. A Denmark study demonstrated shorter diabetes duration was associated with better adherence among adolescent between 12-17 years through the ADQ scale (Kristensen et al., 2018). In a Japanese study, the score of one subscale “self-monitoring of blood glucose and daily life” in the revised diabetes SCI scale was found to be significantly and negatively correlated with diabetes duration, although there was no correlation found between duration of diabetes and total adherence score (Nakamura et al., 2019).

Participants in middle school scored the highest adherence, and those in high school gave the lowest scores in the SCI scale. There were no other articles analysing the relationship between education levels and adherence among children or adolescents with T1DM. However, in this study, the result of adherence in education levels was congruent with the result of self-efficacy, which meant those in middle school also scored the highest self-efficacy. Furthermore, several studies reported that adolescents with higher self-efficacy had higher adherence among adolescents with T1DM (Littlefield et al., 1992, Iannotti et al., 2006, Kristensen et al., 2018). However, the results needed to be interpreted with caution because of the small sample size in this feasibility study. The relationship between diabetes self-management adherence and adolescents' characteristics, including age, gender, diabetes duration and education level, should be re-tested in the future trial with further explanation about underlying reasons.

9.4.2. Changes of adherence at item level

In the SCI scale, Q12 "Wearing a medical alert ID" was given the lowest scores (M=1.38-1.83) at three stages, followed by Q3 "Ketone testing" (M=2.56-3) in this study. Although there were no other studies reporting the detailed items of the SCI scale among adolescents with T1DM, another three studies among adults with diabetes indicated similar results in three different countries. In Pakistan, the mean of Q3 "Ketone testing" (1.37) was reported to be the lowest, and Q12 was also given a third lowest score (2.65) in the 14-item SCI scale (Mumtaz et al., 2016). The 15-item Diabetes Self-Care Inventory-Revised Version (SCI-R) scale and the13-item SCI-R scale were used to test adherence among adults with diabetes in Spain (Jansa et al., 2013) and UK (Khagram et al., 2013), separately, which concluded similar results regarding the two items. In addition to the item "keep food records" with the lowest score, "Wearing a medical alert ID" was scored with the second lowest scores, 2.18 in Spain and 2.15 in the UK, and "Ketone testing" with the third lowest scores, 2.65 in Spain, and 2.40 in the UK. In addition, a survey of ketone testing was conducted among

2995 participants with diabetes in America. Around 50% (n=10) of participants aged 6 years and younger were reported to check ketones "most of the time" or "always" in an American survey, 33% among those aged 6-12 years, 17% among those aged 18-25 years, 7% among those aged 26-49 years, and 11% among those aged ≥50 years (Albanese-O'Neill et al., 2017). Those aged younger than 12 years checking ketones more often may be correlated with parental influence. Further studies are needed to explore the incidence of self-ketone testing and medical alert ID wearing among patients with diabetes in different countries, especially among adolescents.

In this study, three out of five items with the highest scores in the SCI scale were about insulin regulation after working through the web-based material. This may be because insulin treatment was an essential part of daily diabetes management and attracted the adolescents' attention in the web-based material. This was similar to the results of another study which recruited adolescents (11-18 years) with T1DM and parents in Florida (Lewin et al., 2009). In the study, 14 items of the SCI scale were divided into four components to assess, and the component of insulin administration and adjustment was also given the highest adherence scores by both parents and adolescents (Lewin et al., 2009).

In this study, adolescents' adherence on "exercising regularly" and "exercising with great effort" in the SCI scale decreased after working through the web-based material. Although the beneficial impact of regular exercise on health outcomes had been reported among adolescents with T1DM (Quirk et al., 2014, Codella et al., 2017), adolescents still assessed that exercise consistency was challenging for them in this study. The major barriers to exercise for adolescents with T1DM could be evaluated through a qualitative study in the future, which also could provide references for improvement of the educational material.

9.5. Assessment of webpage usability

The System Usability Scale (SUS) was selected to test usability of the webpages developed in this study, including functions, contents and complexity. However, due to a small sample size, only readability and content validity of the SUS scale were evaluated in the feasibility study. The result of webpage usability will be discussed at both scale and item level. Both the scores (0-100) and adjective ratings were used to assess the result. Nevertheless, the results needed to be interpreted with caution because of the small sample size in this feasibility study.

9.5.1. Webpage usability at scale level

(1) Overall usability

The webpages were assessed to be good (79.19) in "Post-test" and excellent (88.75) in "Retest" in this study. It was reported that a score of 70 was acceptable (Bangor et al., 2008). Preliminarily, both the adjective ratings and the SUS scores indicated the webpages were acceptable and usable. Nevertheless, the usability should be retested after reliability and validity testing of the SUS scale in Chinese in a future trial.

The scores of webpage usability increased from "Post-test" to "Retest". However, this result needs to be interpreted with caution because four participants were lost to follow up in "Retest". This may be because the participants found the webpage was less usable. It was hard to know the exact reasons why webpage usability was assessed as being better in "Retest". In a future trial, a qualitative study will be conducted to explore adolescents' experience of webpage usability.

(2) Findings and discussion in subgroup results

Generally, those who were females or in older age group, or had higher formal education level, or had been diagnosed longer preferred to give a better assessment to the webpage usability in this feasibility study. In terms of users' perspective, intellectual development would be one of the possible reasons. The users who had a previous extensive experience to use webpages were also reported to provide higher and more favourable SUS scores (McLellan et al., 2012). In addition, information quality and service quality also indicated to affect users' assessment to E-learning success (Yengin et al., 2011), which provided references for a future trial.

9.5.2. Webpage usability at item level

Among five positive statements or items, only one item was scored with a slight decrease, which is Q7 "I would image that most people would learn to use the webpages very quickly". However, all the participants gave a score of 4 or 5 on this item at both stages, which meant they agreed or strongly agreed the webpages would be easy to learn for most people.

All five negative statements were scored with a decrease to different degrees, which meant better assessment of webpage usability. The item Q10 "I needed to learn a lot of things before I could get going with the webpages" was scored with the greatest decrease from Part three "Post-test" to Part four "Retest". The mean of Q10 in "Post-test" (4.33) was far higher than the means of other four negative items (1.33-2.11) at two stages, which did not happen in the previous study (Bangor et al., 2008). This may be caused by misunderstanding of this item among Chinese participants because the translation did not reflect the negative meaning. This item should be reworded in a future trial.

9.5.3. Implications of key findings for the webpages developed

Although the sample size was small in this feasibility testing study, several implications of the key findings were summarised for the webpages, which could be helpful for webpage development and maintenance in diabetes education researches.

First, as mentioned before, after studying the web-based type 1 diabetes educational material, diabetes knowledge, self-efficacy and adherence improved among adolescents with T1DM. This indicated that the webpages played an irreplaceable role in diabetes self-management among adolescents with T1DM. The webpages could be generalised for adolescents' self-care in China if the web-based material is tested to be effective in future.

Second, diabetes knowledge increased after studying the web-based material in Part three "Post-test", but decreased in Part four "Retest" in this study. Repeated learning could help adolescents better understand the web-based material. In addition, regular update is also a good way to attract adolescents to keep studying on the webpages.

Moreover, the webpage usability was assessed to be good to excellent in the System Usability Scale, however, the retention rate was lower than expected in this study. A semi-structured interview could be beneficial to find out what adolescents like or dislike about the details of the webpages to improve both webpage usability and retention rate.

9.6. Feasibility and limitation of the study

9.6.1. Feasibility of this study

This study was found to be feasible at the preparatory stage, including development and validity testing of a type 1 diabetes educational material, development of the phone-based webpages, and selection and validity testing of four scales. However, at data collection stage, it showed a low feasibility in participant recruitment and retention.

First, this study demonstrated that the development and validity testing of a type 1 diabetes educational material in English or Chinese was highly feasible. In this study, the material was developed in English, which was translated forward by me and backward by other four colleagues of mine. The readability of the material was tested by sending the material to seven adolescents without diabetes at the age of 10-19 years to read because no appropriate tool was available, like Microsoft Word, to test readability of Chinese. The material was assessed to be readable and easily understandable. Two-round content validity was tested by 10 multidisciplinary experts in China to ensure the material was scientific and clinically accurate.

Second, development of webpages was possible in the nursing research, although I had no experience of webpage development before. Considering budget and target populations, mobile webpage was selected in this study, rather than computer webpage or mobile app. Before publishing, the webpages were tested among me and an adolescent with T1DM.

Third, selection of scales which were consistent with the purpose of this study and content validity testing were possible, which are presented at five steps: 1) systematic searching and review were conducted to identify scales which can be used among adolescents with T1DM; Three scales in English to test self-efficacy (SEDM), adherence (SCI) and webpage usability (SUS) were selected; 2) a type 1 diabetes knowledge scale (T1DK) with 10 items was developed by analysing the common content structures of existing scales; 3) the four scales were translated forward and backward according to WHO translation guideline with transcultural adaptation; 4) the four scales were tested to be readable and easily understandable among seven adolescents at the age of 10-19 years in China; and 5) face and content validity testing of the four scales were conducted in multidisciplinary experts' team. Content validity of the new developed T1DK scale was also tested to be acceptable with adding two other items about low blood glucose and DKA.

Fourth, 16 participants registered on the webpages and six of them fully completed the feasibility study, which was demonstrated to have a low feasibility because of relatively low recruitment rate and completion rates in each of four parts of the webpages. This will be mentioned further.

According to the CONSORT 2010 checklist which provided reporting guidance for the reporting of randomised pilot and feasibility trials (Eldridge et al., 2016), this feasibility study tested and reported all related items mentioned in the checklist. However, there are some limitations, lessons and improvements found during implementation of this study, which are presented at following three parts.

9.6.2. Lessons or reflections from the study

The main lessons at both data collection and preparing stages are presented, which could provide references for the future trial or other researchers:

(1) The first and main lesson is that a text or a phone call may not be a good method to recruit participants in China, although the hospital information system was found to be a good method to find potential participants. The main reason is the sense of mistrust between strangers, which exists in Chinese culture (Wilson and Gyi, 2010, Shen et al., 2013), even among Chinese immigrants (Limkakeng et al., 2013), which was overestimated in participant recruitment by me before the feasibility study.

(2) In this study, webpage was selected as the means to educate adolescents with T1DM, rather than an app, because it is much more expensive to develop and maintain an app-based education research (Luxton et al., 2014). However, a review reported that mobile apps were preferred by users more than websites (Fontelo and Liu, 2013). A study

explored the effects of web-based and app-based blood sugar management on compliance among adults with diabetes in Australia. Although there was no significant difference in compliance in the two groups, 68% of men and 95% of women preferred to choose the app method (Schreier et al., 2012). In addition, the effectiveness of web-based and mobile app-based education on compliance of diabetes regimen needs to be explored among adolescents with T1DM in the future.

(3) During the development of the type 1 diabetes educational material, two aspects should be considered. The first is how to assure that the content framework of the material is scientific. In this study, the ISPAD guideline developed for children and adolescents with diabetes and the theory of the Health Belief Model were combined to provide the content framework for the material. The second is about copyright of the images which were used in the material. In this study, to achieve high readability, the images from Google Images were used to attract adolescents' interest, to illustrate definitions or difficult contents, and to improve their compliance to complete the study. The copyright of these images should be considered. In this study, the images were selected and used only if they were labeled for reuse. However, a qualitative study will be conducted in the future trial to explore whether there is any problem in the material reducing the retention rates.

(4) With regards to the scales, there were also two important lessons. First, the number of items in the scales was considered to improve the compliance of scale completion because the target participants were adolescents from 10-19 years. Second, completing scales on the webpages would be a good way to avoid incomplete scales. In this study, participants would be reminded to submit the scales after fully completed if they fail to finish certain items. However, to identify whether there are any scale-related reasons of reduced completion rates, a qualitative study will be conducted in a future trial.

9.6.3. Limitation from the study

First, this was a feasibility testing study with a small sample size, which was also related to lower percentage of T1DM in children and adolescents.

1) According to International Diabetes Federation (IDF) Diabetes Atlas, China had 114.4 million adults (20-79 years) with diabetes and 47,000 children and adolescents (<20 years) with type 1 diabetes in 2017 (IDF, 2017);

2) Participants were only recruited from one university hospital (the Affiliated Hospital of Southwest Medical University) in China. Although the hospital contains 3200 open ward beds and had 140,000 inpatients in 2019, only 85 adolescents aged between 10 to19 years were diagnosed with T1DM from 2014 to 2019 and treated. Therefore, participants recruited in a hospital in this study could not be representative of the larger population (10-19-year adolescents with T1DM) in China.

3) The study was only funded by the university hospital with limited financial support;

4) Time limitation during PhD studying also contributed to the small sample size in the study.

Second, low recruitment and completion rates were another limitation. However, recruitment was only conducted in one hospital, recruitment methods also contributed to a lower recruitment rate. Text message and phone calls were thought to be appropriate to recruit patients in China because more than 800 million people were reported to use phone in June 2019 (CNNIC, 2019a) and around 155 million minors (<18 years) accessed the internet through smartphone in 2018 (CNNIC, 2019b). However, mistrust was the main barrier of recruitment (Wilson and Gyi, 2010, Shen et al., 2013), which was underestimated in designing the proposal of the feasibility study. Another reason would be that there was no special retention proposal and strategy to improve the completion rates in this study. This was because the type 1 diabetes material developed in this study gained favourable comments during readability testing in adolescents. In addition, 85.3% of children and adolescents at the age of 6-24 years surfed the internet in 2015 in China (CNNIC, 2016). Therefore, I overestimated the popularity of the web-based educational material among adolescents.

Third, about the characteristics of participants recruited in this feasibility, adolescents in the 10-12 age group and 13-15 age group were relatively fewer, and fewer males were recruited. Although female adolescents were found to have a higher incidence of type 1 diabetes in this area, a proposal also should be made to encourage younger and male participants to take part in the future trial.

Fourth, there were some other limitations regarding study design. Although the System Usability Scale (SUS) was selected to assess the webpage usability and participants assessed the webpages to be a good or excellent in this scale, only six participants fully completed the webpages, which seemed to be contradictory. However, participants' thoughts and experience were not acquired after they completed the web-based T1DM material owing to lack of ethic permission in this study. Furthermore, this feasibility study only lasted around 3 months, and the long-term effect of the web-based material also could be assessed in the future trial.

9.6.4. Improvements to be made in a future trial

According to the limitations mentioned before, some improvements will be considered and made in a future trial. First, a qualitative study will be conducted among participants in the future to explore their experience of webpage usability, the T1DM material and the four scales, which can provide reference for the improvement of a future trial. In addition, the T1DM educational material and the scales will be checked, discussed and modified according to problems met in the feasibility study, such as rewording the last question (Item 10) of the System Usability Scale (SUS) scale.

Second, to ensure an appropriate sample size, participant recruitment will be extended to different hospitals or even different cities in China, which needs more financial support and assistance. Therefore, fund application will be an essential part to conduct a future trial. In addition, ethic permission will be also needed to conduct recruitments in other hospitals or cities.

Third, four aspects of strategies will be considered to improve the recruitment and retention rates.

- Although the sense of mistrust exists between patients and health care practitioners in China, roughly 70% of Chinese patients indicated that their doctors' mention or recommendation was likely to affect their decision to take part in a study (Wu et al., 2015). Therefore, the involvement of patients' doctors or nurses will be considered to enforce the sense of trust in parents and adolescents.
- Several recruitment methods will be combined to recruit patients, including technology-based advertising (WeChat or official hospital webpages) and snowballing.
- Regular and continuing contact will be considered to improve the retention rate after gaining ethical permission.
- Appropriate amount of money or a certain value of material incentives will be used to encourage a full completion of the webpages, such as film gift certificates, blood glucose test strip or blood lancet, or retail store gift voucher.
- To improve recruitment and retention rates of younger or male adolescents, their requests will also be considered in building incentive strategies.

9.7. Implications for research, education in practice and policy

• Implications for research

The result of this research answered the question: can web-based type 1 diabetes educational material be developed for adolescents with T1DM in China? At the preparation stage, type 1 diabetes educational material with 17 diabetes self-management "topics" and the webpages in accordance with the educational material was developed and tested to be easily understood with acceptable content validity. At the data collection stage, although the recruitment and retention rates were lower than expected, 16 participants registered on the webpages, and six fully completed. Therefore, the topic is worthy of further exploration, and the proposal for the future trial will be described in chapter 11. In addition, another two aspects will be considered in future studies for other researchers.

1) As mentioned in chapters 8 and 9, adolescent recruitment and retention will be a difficulty in most health research, not only in this study. In this research, participant-, cultural-, study-, and organisation-related factors were discussed, which could provide reference for the future trial and other researchers.

2) Users have been increasingly encouraged to be involved in designing nursing research, especially in the field of education interventions and new-technology based programmes (Nies & Pelayo, 2010). In this study, owing to limited time and resources, adolescents were not included in design of the educational material and the webpages; however, a qualitative study will be conducted after obtaining ethical permission to glean adolescents' suggestions about the material, the webpages and scales developed in this study. In future, users' requirements will be considered and incoportaed appropriately.

- Implications for education/nursing in practice

Although generalisation was not possible because of the small sample size in this study, several implications could be helpful for nursing in practice, especially diabetes education in clinics.

First, the health belief model (HBM) could be a good tool to guide diabetes education and could be used to investigate the individualised factors that affect adherence to diabetes self-management regimes, according to the six core content constructs. In addition, people's self-efficacy should also be considered as an essential aspect to improve the efficacy of diabetes education interventions.

Second, people should be actively involved in the educational process, rather than through top-down didactic teaching methods common in China.

Moreover, the educational materials should be scientific and understandable for users. The educators should also give individualised education to people with diabetes or caregivers according to their age, stage of diabetes, lifestyle and education level.

- Implications for policy making

There is still a significant gap in diabetes education between China and some western countries, such as the UK and USA. Diabetes education has been regarded as an optional method in the management diabetes in China, rather than a mainstream approach. Several aspects should be considered by the policy makers in China:

1) An internal diabetes education system should be built to guide diabetes education research and practice, such as guideline and standard making, management of diabetes educators and programmes.

2) Training, certification, continuing educations of diabetes educators need to be explored, which could be based on Chinese culture and experience from those western countries.

3) The management of programmes or curricula is also important; this should be evidence-based, up-to-date and individualised. Repeated and ongoing education should be more beneficial, especially for younger adolescents.

9.8. Conclusion of the study

The study design at the preparatory stage indicated to be feasible. It proved to be possible to develop a type 1 diabetes educational material with a good readability and content validity, to develop the webpages with good or excellent usability, and to select appropriate scales with good readability and content validity.

However, it had a lower feasibility at the data collection stage due to the lower recruitment and retention rates. The recruitment and retention rates need to be improved through at least four aspects of strategies, including the involvement of patients' doctors or nurses, combined recruitment methods, regular and continuing contact with participants and parents, and monetary or material incentives.

Table 9.1 summarises what is already known about new technology-based diabetes education and care, and what this study adds, as well as the improvement which will be made in a future trial.

Table 9.1. Conclusion of diabetes education in adolescents with type 1 diabetes

Items	Contents
What is already known about this topic	1.Education is the key of successful diabetes management. 2.The ISPAD guideline recommended to use new technologies in diabetes care as one of the vehicles for educational motivation. 3.The new-technology based diabetes education and care has been widely explored and conducted among adolescents with T1DM in developed countries. 4.A recent systematic review showed only one RCT exploring this topic in China. Therefore, the effects of new-technology based diabetes education or care need to be explored further in Chinese adolescents with T1DM.
What this study adds (a feasibility study)	1.It is possible to design a type 1 diabetes educational material in Chinese, which is understandable for adolescents and contains scientific contents. 2.It is feasible to develop webpages for Chinese adolescents with easy navigation. 3.It is possible to select appropriate scales to test self-efficacy, adherence and webpage usability among Chinese adolescents, and to develop a new scale to test diabetes knowledge among them with good readability and content validity. 4.Text and phone calls are not good methods to recruit patients in China. Lower recruitment and retention rates were found in this feasibility study, which need to be addressed and improved in a future trial.
What will be improved in the future trial	Several strategies will be considered to improve the recruitment and retention rates in the future, including: • involvement of patients' doctors or nurses; • combining several recruitment methods; • regular and continuing contact; • money or material incentives;

CHAPTER 10 PROPOSAL FOR A FUTURE TRIAL

In this chapter, a proposal consists of two steps, including a pilot study with improvements of recruitment and retention strategy and an effectiveness testing study as shown in figure 10.1.

1) A pilot will be conducted to test the feasibility of the renewed recruitment and retention strategies, and to test reliability and construct validity of the four scales in Chinese. The CONSORT 2010 checklist to report a pilot or feasibility trial provides reference for the proposal of the pilot.

2) An effectiveness testing study will be conducted to test the effects of the web-based material on knowledge, self-efficacy and adherence during Chinese adolescents.

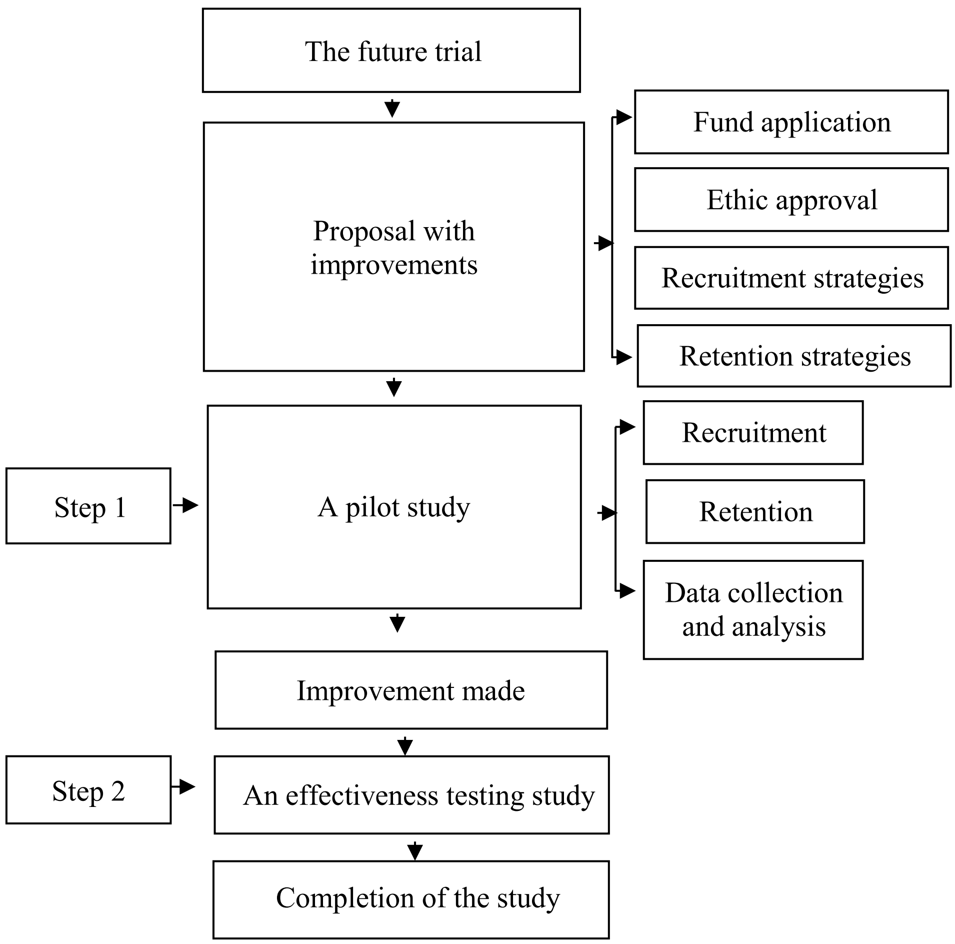


Fig 10.1. Flow chart of the proposal in the future trial

10.1. Step 1: a pilot study

A pilot study refers to a small study or a miniature version of the main study to design a further confirmatory study. In this study, low recruitment and retention rates in the feasibility study need to be improved with new strategies, and reliability and construct validity of the four scales need to be tested before the main study, which are why the pilot study will be conducted firstly. In this new study, the pilot study will be the first phase of the main study before exploring the effectiveness of the webpages-based education in Chinese children and adolescents.

10.1.1. Aims of the pilot study

- To test the new recruitment and retention strategies;
- To test reliability and construct validity of the four scales selected or developed in the feasibility study, including internal consistency, test-retest reliability and exploratory factor analysis (EFA);
- To estimate parameters to calculate the sample size in the effectiveness study;

10.1.2. Study design and registration

A before and after pilot study will be conducted at this step. The pilot study will be registered before implementation on the webpage of Chinese Clinical Trial Registry (ChiCTR) http://www.chictr.org.cn/abouten.aspx, which was established is 2005, and assigned to be the representative registry of China to join the WHO ICTRP in 2007.

10.1.3. Participant and sample size

(1) Inclusion and exclusion criteria

Inclusion criteria: adolescents who are at the age of 10-19 years and have been diagnosed with T1DM will be included; adolescents are able to understand spoken and written Chinese; a smartphone is available for adolescents to use at home or in the school. **Exclusion criteria:** Those who have severe hearing or vision impairment which will affect material reading or communication with me will be excluded.

(2) Sample size estimation

In this pilot study, reliability and validity of the four scales will be tested, including internal consistency, test-retest reliability and exploratory factor analysis (EFA). EFA will be used to describe the underlying conceptual structure of the four scales. Sample size is an important factor for ensuring stable factor structures in the EFA process (Ferguson and Cox, 1993). According to the article (Costello and Osborne, 2005), subject to item ratio was used to estimate the sample size of EFA by researchers, which ranged from 2:1 or less to 100:1 or more. However, among 62.9% of studies, researchers performed analyses with subject to item ratios of 10:1 or less, which is still a prevalent rule-of-thumb many researchers use to determine a sample size.

In this pilot, participant to item ratio of 10:1 will be used. The numbers of items in the four scales ranged from 10 to 14. Therefore, the number of subjects need to be at least 140. The rate of lost to follow-up in this pilot will be set as around 30% after the involvement of retention strategies. Therefore, the sample size in this pilot should be no less than 182 (140 + (140×30%)) participants.

10.1.4. Fund application and ethic approval

Considering that participant recruitment will be expanded and incentives will be considered to be provided for participants, extra financial support will be needed through fund application. Ethical approval will be reapplied because of four different designs in the pilot: 1) the recruitment will be expanded in different hospitals or even cities; 2) recruitment and retention strategies will be modified, which will be mentioned in the following part; 3) doctors or nurses in different hospitals will be involved to recruit potential participants; and 4) quantitative semi-structured interviews with participants will be considered with informed consent to know participants' experience.

10.1.5. Participants recruitment strategy

Based on the experience of the feasibility study, the recruitment strategies will be improved in following four aspects to recruit enough participants in the pilot study.

• Expanded hospitals or areas to recruit participants

Recruitment areas will be expanded. By using convenience sampling methods, another two hospitals (tertiary hospitals) in Luzhou which have cooperative relationship with the Affiliated Hospital of Southwest Medical University will be screened to find potential participants. If the number of participants is not sufficient, the tertiary hospitals in neighbouring cities of Luzhou (Sichuan Province), including Yibin and Zigong, will be screened, and so on.

• Combined recruitment methods

The recruitment methods need to be modified because of mistrust between strangers in China. This may become more serious if the recruitment will be expanded to other hospitals or even other cities. The involvement of patients' doctors or nurses would be a method to enforce the sense of trust. In addition, several methods will be combined to recruit participants, including advertising on WeChat (the most popular social media), in hospitals or on official hospital webpages, face-to-face recruitment and snowballing. Although phone call was demonstrated to be not a perfect method to recruit participants, it will still play an important role during recruitment because of its convenience.

- Extended recruitment duration

Recruitment duration will be expanded to six months, or even 12 months;

- Detailed recruitment process (a preparing stage and a recruiting stage)

First, in the preparing stage, it will spend much time to advertise in the wards, on the official hospital webpages, and through WeChat.

Second, the hospital information system will be checked to find the contacting details of potential participants.

Third, in the recruitment stage, different from the feasibility study, patients' doctors' or nurses will be invited in the pilot study to introduce the research to parents and adolescents. Face-to-face recruitment will also happen when adolescents go to see their doctor for regular clinic visit, and doctors will also be invited to introduce the study to adolescents with T1DM and parents. However, adolescents and parents will be given the freedom and respect to decide whether they prefer to participate or not.

Fourth, further contacting information will be given to those who are interested in participating the study. Parents or adolescents can contact to know more about the study and register on the webpages after signed the consent form.

10.1.6. Interventions

The intervention of this pilot study is consistent with that in the feasibility study, which consists of registration of the webpages in four parts, finishing three scales about diabetes knowledge, self-efficacy and adherence in Part one "Pretest", studying a type 1 diabetes educational material in Part two "education", completing four scales (including a scale about webpages usability) in Part three "Post-test" and Part four "Retest".

10.1.7. Participants retention strategy

According to the experience of the feasibility study, retention strategy will be developed to improve the completion rate in the pilot study. The specific strategies consist of regular and continuing contact and appropriate incentives.

Participants and their parents will be contacted every week through phone call to review participants' progress, their attitudes towards the research, and whether adolescents or parents have any problems about their diabetes management. Parents will be encouraged to be involved in the webpages studying process. The date and time to make calls will be appointed with adolescents or parents at the previous call.

In addition, participants will be given a chance to choose their own incentives, including a certain amount of money, or a certain value of material incentives, such as blood glucose test strip or blood lancet (relatively expensive for patients in China), or retail store gift voucher.

10.1.8. Outcome measures

(1) Quantitative measures

- Recruitment and retention rates

Recruitment rate would be acceptable if recruitment rate is between 25% and 40%. The full completion of the webpages will be calculated, which will be acceptable if it is more than 70%.

• Reliability (internal consistency, Test-retest reliability) and construct validity (EFA)

Cronbach's α (or coefficient α) will be used to measure the internal consistency, which would be acceptable if Cronbach's $\alpha \geq 0.7$. Intraclass correlation coefficient (ICC) is selected to evaluate the test-retest reliability. There is no standard value for acceptable reliability using ICC. However, it is suggested that ICC values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values greater than 0.90 indicate excellent reliability. The exploratory factor analysis (EFA) will be conducted to explore the underlying theoretical structure.

• The preliminary effectiveness of the webpage-based education

Paired t-test will be used to test preliminarily if there are significantly differences between diabetes knowledge, self-efficacy and adherence before and after studying the webpage-based material. If $P<0.05$, the results will be recognised to be statistically significant. If $P\geq 0.05$, the results will be not significant.

(2) A qualitative study

A qualitative study with semi-structured interviews will be conducted to explore participants' experience of the web-based T1DM material, which would provide reference for improvement of the effectiveness study. Adolescents will be invited in individuals or groups (6-12 participants) to discuss their experience and thoughts about the recruitment, retention and usability of the webpages, including the webpage format and design, content of the type 1 diabetes educational material, and the four scales.

10.1.9. Data collection and analysis

The data collection of the quantitative study will be conducted through the four scales on the webpages developed in this study. The two engineers who developed the webpages will undertake the responsibility to maintain the webpages. The webpages are password-protected to safeguard participants' personal information. Semi-structured interview in regular clinic visit or on phone will be considered according to participants' aspiration.

The data analysis will be conducted using SPSS and NVivo software. Any publications will be published void of participants' personal details.

10.2. Step 2: an effectiveness testing study

The effective testing study will be planned according to the results of the pilot study, especially the effects of the recruitment and retention strategies, and feedbacks from the qualitative study.

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APPENDICES

Appendix 1: The systematic review published in Chinese in 2017--Chapter 2

基于网络和手机的信息技术对1型糖尿病儿童和青少年血糖管理影响的系统评价

赵小磊,郑思琳,黄厚强

摘要:[目的]评价网络、手机等现代信息技术对1型糖尿病儿童和青少年血糖管理的影响。[方法]检索Cochrane图书馆、Joanna Briggs Institute Library、PubMed、EMbase、CBMdisc、CNKI、万方等数据库中关于网络、手机对1型糖尿病儿童和青少年血糖管理影响的随机对照试验。采用Cochrane handbook 5.1.0对文献进行质量评价,利用Revman 5.3进行Meta分析。[结果]共纳入14篇随机对照试验,其中英文13篇、中文1篇。网络、手机等信息技术不能帮助1型糖尿病儿童和青少年有效控制血糖[WMD=-0.09,95%*CI*(-0.21,0.02),*P*=0.12],其中网络对1型糖尿病儿童和青少年的血糖控制没有影响[WMD=-0.09,95%*CI*(-0.11,0.29),*P*=0.35],手机反而会使1型糖尿病儿童和青少年的血糖控制不良[WMD=-0.18,95%*CI*(-0.32,-0.04),*P*=0.01];网络、手机等信息技术不能减少胰岛素使用量[WMD=0.06,95%*CI*(-0.06,0.19),*P*=0.32]。[结论]网络和手机等不能帮助1型糖尿病儿童和青少年进行有效的自我管理,但鉴于纳入研究的结局指标异质性较大,文献质量不高,样本量较小,因此尚需要更多设计合理、具有客观统一结局指标的大样本、高质量研究,以获得更可靠的证据。

关键词:网络;手机;1型糖尿病;儿童;青少年;血糖管理;系统评价;Meta分析

A systematic review of effect of information technology based on network and mobile phone on blood glucose management in children and adolescents with type 1 diabetes mellitus

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Abstract **Objective**: To evaluate the effect of modern information technology such as network and mobile phone on blood glucose management in children and adolescents with type 1 diabetes mellitus. **Methods**: Randomized controlled trials (RCT) of network and mobile phone effect on blood glucose management in children and adolescents with type 1 diabetes mellitus were retrieved among Cochrane Library, Joanna Briggs Institute Library, PubMed, EMbase, CBMdisc, CNKI, Wanfang data and other databases. The quality of the literature was evaluated using Cochrane handbook 5.1.0, and meta-analysis was performed using Revman 5.3. **Results**: A total of 14 RCTs were included, of which 13 were in English and 1 was in Chinese. Network, mobile phone and other information technology cannot help type 1 diabetes children and adolescents to control the blood glucose effectively [WMD=-0.09, 95%*CI* (-0.22, 0.02), *P*=0.12], in which the network has no effect on blood glucose control of type 1 diabetes children and adolescents [WMD=0.09, 95%*CI*(-0.11, 0.29), *P*=0.35], while the mobile phone could decrease the control of blood glucose in type 1 diabetes children and adolescents [WMD=-0.18, 95%*CI* (-0.32, -0.04), *P*=0.01]. The application of modern information technology such as network and mobile phone cannot reduce the use of insulin [WMD=0.06, 95%*CI* (-0.06, 0.19), *P*=0.32]. **Conclusions**: The network and mobile phone did not contribute to the effective self-management of children and adolescents with type 1 diabetes mellitus. However, since the heterogeneity of the outcome index was large, the quality of the literature was not good, and the sample size is small, there still need more reasonable design, union objective outcome of a large sample, and high-quality RCTs, in order to obtain a more reliable evidence.

Keywords network; mobile phone; type 1 diabetes mellitus; children; adolescents; blood glucose management; systematic evaluation; meta-analysis

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1型糖尿病是儿童青少年慢性代谢性疾病中最普遍、最严重的一种疾病,约占糖尿病人群的5%~10%。据国际糖尿病联盟(International Diabetes Federation,IDF)报道,2015年全球1型糖尿病儿童的数量首次超过50万人,且以每年3%的速度增长[1]。儿童青少年糖尿病的控制目标是维持血糖水平接近正常状态,保证其正常的身心发育,这对处于生理和心理转变阶段的儿童青少年病人来说是极具挑战性的[2]。

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短信服务、手机 APP、电子监测器等现代移动信息技术越来越多地被运用于 1 型糖尿病儿童及青少年,以加强疾病的自我管理,促进健康行为的改变。虽然目前关于移动信息技术对 1 型糖尿病儿童和青少年血糖管理影响的研究较多,但干预方案(途径、频率、持续时间等)和结局指标都存在较大差异。本研究旨在评价网络、手机等移动信息技术的应用对提高 1 型糖尿病儿童和青少年血糖管理的效果。

1　资料与方法

1.1　检索策略　系统评价检索中文/英文公开发表的随机对照试验(RCT)。以英文关键词"internet/mobile phone/smartphone, type 1 diabetes mellitus/T1D, children/kids/adolescents/youth, self-management/quality of life"检索 Cochrane 图书馆、Joanna Briggs Institute Library、PubMed、EMbase。以中文关键词"网络/手机/APP、1 型糖尿病、儿童/青少年、自我管理/疾病管理/血糖控制"检索中国生物医学文献数据库、中国期刊全文数据库、万方数据库。文献检索过程包括:①在上述中英文数据库中检索系统评价/Meta 分析;②在数据库中检索原始文献,并对其题目、摘要、关键词和主题词进行分析,进一步确定本研究的关键词;③运用所得关键词和主题词对所有数据库进行检索;④通过追溯参考文献进一步保证文献查全。

1.2　文献纳入和排除标准

1.2.1　研究类型　选择比较移动信息技术和常规护理在提高 1 型糖尿病儿童和青少年血糖管理的随机对照试验。

1.2.2　纳入及排除标准　纳入对象:年龄≤23 岁的儿童和青少年,诊断 1 型糖尿病>6 个月;能够在家、医院、社区上网或使用手机的病人。排除对象:病情危重者;意识不清楚或者有严重并发症者;有精神障碍或其他精神疾病史病人;合并其他慢性疾病的病人。

1.3　干预措施　试验组利用网络、手机 APP、短信服务及其他电子设备和信息技术对 1 型糖尿病儿童和青少年进行疾病血糖管理,对照组接受糖尿病常规护理。

1.4　结局指标　主要结局指标为糖化血红蛋白(Hb1Ac),次要结局指标主要为胰岛素使用量。

1.5　文献质量评价　由 2 名参加循证培训的研究人员根据 Cochrane handbook 5.1.0 对文献进行独立质量评价:①随机序列的产生;②是否做到分配隐藏;③是否对参与者和实施者采用盲法;④是否对结局评价者采用盲法;⑤结局指标数据的完整性;⑥是否有选择性报告研究结果;⑦其他方面的偏倚。完全满足上述标准,发生偏倚的可能性最小,为 A 级;部分满足上述质量标准,发生偏倚的可能性为中度,为 B 级;完全不满足上述质量标准,发生偏倚的可能性为高度,为 C 级。2 名研究人员独立评价文献质量后,对筛选及评价结果进行比对,意见不一致时由两人讨论达成共识或请第三方仲裁。

1.6　资料提取　2 名研究人员阅读全文后进行资料提取,内容包括:纳入/排除标准、纳入对象的年龄、性别比、样本量、研究持续时间、干预措施、结局指标和失访率等。结局指标中连续性指标用均数和标准差($\bar{x}\pm s$)表示,如果原文中没有报道均数或标准差,则根据张冰等[3-4]文献报道,利用可信区间和样本量进行转换。

1.7　资料分析　利用 Revman 5.3 进行 Meta 分析。采用均方差(WMD)和 95%*CI* 为指标分析统计量,首先确定研究间是否存在异质性,$P>0.1$,$I^2<50\%$可认为多个研究具有同质性,选用固定效应模型进行 Meta 分析;如果 $P<0.1$,$I^2\geqslant50\%$,则选择随机效应模型,同时进行敏感性分析。如异质性过大且无法判断来源,则采用描述性分析。

2　结果

2.1　纳入研究的一般情况　初检出相关文献 1 386 篇,其中英文 1 378 篇、中文 8 篇。剔除重复文献、与主题不相关和明显不符合纳入标准的文献 1 281 篇;阅读题目和摘要排除综述类、非随机对照实验、无对照组的临床试验 61 篇;进一步阅读全文,排除纳入对象及年龄、干预措施和结局指标不符合的文献 30 篇,最终纳入 14 篇随机对照研究,其中英文 13 篇、中文 1 篇。

2.2　纳入文献的基本特征　本研究纳入文献 14 篇,其中英文 13 篇,中文 1 篇,涉及 1 070 例病人,多为诊断 1 型糖尿病至少 6 个月以上的病人。有 10 篇文献报告了性别构成,其中干预组男 201 例,女 201 例;对照组男 214 例,女 183 例。研究持续时间从 7 周至 18 个月。干预方式主要包括 3 类:利用网络平台与病人互动(10 篇);通过打电话追踪病人疾病管理(2 篇);利用短信提醒病人,提高其疾病管理的依从性(2 篇)。其中网络干预内容多样,主要包括:病人定期上传自己监测的糖尿病数据,专家查看并反馈;专家通过网络电话或远程系统,为病人提供培训和指导;研究团队建立网络平台,为病人提供讲座,或者让病人加入论坛、聊天室,促进病人之间、病人与专家之间的交流;加强青少年病人的心理教育;鼓励家属参与到病人的疾病管理中来。纳入文献的基本特征见表 1。

表 1　纳入研究的基本特征

纳入研究	纳入/排除标准及失访率	年龄 岁	性别(男/女) 例	样本量(例) T	样本量(例) C	干预持续时间	干预方式 T	干预方式 C	结局指标及评定时间
Lawsona 等[5]	纳入：13 岁～17 岁 1 型糖尿病青少年病人；疾病诊断超过 1 年；每天使用胰岛素 2 次或 3 次，血糖控制较差（前 6 个月 HbA1c>8.5%）。排除：合并其他慢性疾病；正在治疗的甲减和哮喘，口服糖皮质激素每年少于 2 次。失访率 15.2%	T：15.4±1.3 C：15.0±1.2	T：14/9 C：12/11	23	23	6 个月	标准护理＋电话干预：糖尿病教育护士每周给病人打电话了解病人上周血糖情况，并给病人提供关于胰岛素调整的建议	标准护理：皮下胰岛素注射；每天监测血糖 3 次；制定糖尿病饮食计划；医生定期访病人；监测 HbA1c	结局指标：HbA1c、依从性（CDMS 量表）、生活质量（DQOLY 量表）、家庭环境问卷、每天胰岛素使用量、BMI、糖尿病不良事件。评定时间：基线、3 个月、6 个月
Franklin 等[6]	纳入：8 岁～18 岁的 1 型糖尿病年轻人；诊断糖尿病超过 1 年；进行传统胰岛素治疗的病人。排除：有严重的社交问题、严重的学习障碍、对注射恐惧的病人。失访率 1.6%	T：14.1±1.0 C：12.7±1.1	T：15/18 C：17/10	33	27	12 个月	传统的胰岛素治疗＋Sweet Talk：一种动机支持的网络，研究者通过手机短信，发送一些在理论上具有指导意义的干预行为，加强病人自我管理和控制	传统的胰岛素治疗：由多学科团队提供，每 3－4 个月进行 1 次临床访视，有权拨打急诊热线	结局指标：HbA1c、DKA 低血糖等急性并发症的发生率、糖尿病自我效能量表、视觉模拟依从量表、糖尿病认知量表、糖尿病社会支持访谈得分等。评定时间：基线、12 个月
Rami 等[7]	纳入：HbA1c≥8%；患病>1 年；10 岁～19 岁的 1 型糖尿病病人；愿意加入本研究；同意坚持 3 个月随访 1 次。失访率未报告	T：14.5±1.6 C：16.2±2.1	T：9/9 C：11/7	18	18	3 个月	病人每天将测得的血糖、食物糖类的含量等数据发送到 VIE－DIAB 平台；记录糖尿病日志；每周病人将得到一条系统自动生成的短信，或者具有特定建议的个性化短信	写纸质日记＋定时随访	结局指标：HbA1c、并发症发生率、胰岛素使用量、病人满意度。评定时间：基线、3 个月
Nunn 等[8]	纳入：3 岁～16 岁；疾病诊断大于 12 个月；前 6 个月平均 HbA1c≥8%。失访率 11.5%	T：11.9±3.7 C：11.9±3.0	T：33/27 C：36/27	60	63	7 个月	教育者每月 2 次向病人提供电话讨论，每次 15 min～30 min；讨论内容包括胰岛素的使用、二氧化碳的摄入、不良事件及教育方案等。除了预期电话，病人也可能收到随访电话	病人可以通过电话联系糖尿病团队成员；但没有安排预期电话	结局指标：HbA1c、再住院率、矫正的糖尿病认知量表；优势和困难量表、社会和家庭功能指标。评定时间：基线、7 个月
Newton 等[9]	纳入：11 岁～18 岁的 1 型糖尿病病人。失访率 5.1%	未报告	未报告	38	40	12 周	每天穿戴计步器，共 12 周，计步器会自动记录步行数；病人每天至少行走 10 000 步，参与者每周会收到短信提醒其穿戴计步器	标准护理	结局指标：活动量的改变、自我报道在过去 7 d 的活动量、血压、BMI、生活质量。评定时间：基线、12 周
Mulvaney 等[10]	纳入：13 岁～17 岁；疾病诊断超过 6 个月；能使用互联网；会讲英语。排除：对网站内容理解有障碍者。失访率 5.1%	未报告	未报告	34	18	11 周	多学科合作的糖尿病专家团队和年轻病人一起编辑网站内容。其他活动包括：个性化的主页，通过同龄人社团建立社交网络，获得来自专家的帮助等	常规护理	结局指标：HbA1c、行为测量、依从性（DBRS 量表）、解决问题（DPSBS 量表）。评定时间：基线、11 周
Landau 等[11]	纳入：11 岁～20 岁的 1 型糖尿病病人；疾病诊断至少 6 个月；愿意加入研究；能坚持每月 1 次的随访；没有记录在案的精神障碍。失访率 0	T：15.1±2.7 C：15.1±2.4	T：15/21 C：17/17	36	34	6 个月	病人每周将自己监测的血糖值上传至网络，并联系协调者，协调者再登录网址查看数据；经过与内科医生协调，给参与者电话回复；假如参与者血糖控制差，临床工作人员会通过电话联系病人	病人自己查看血糖监测结果；所有参与者可以获得面对面糖尿病护理，每 3 个月 1 次或者按需护理	结局指标：HbA1c、严重低血糖和 DKA 的发生率、病人满意度等。评定时间：基线、3 个月、6 个月
Newton 等[12]	纳入：13 岁～18 岁；能在家上网；有网络聊天的经验。排除：疾病诊断<6 个月；使用胰岛素泵 6 个月之内。失访率 15.3%	T：14 C：15	T：5/20 C：13/12	25	25	7 周	标准的医疗护理＋网络干预：参与者每周至少登陆平台 3 次，更新博客、参与论坛和聊天，满足基本要求的可以参加抽奖，研究结束后，研究团队会举办 Pizza 派对，加强交流	获得标准的医疗护理	结局指标：生活质量（DQOLY 量表）、自我效能、自我管理的结果期待等；评定时间：基线、7 周

(续表)

纳入研究	纳入/排除标准及失访率	年龄 岁	性别(男/女) 例	样本量(例)		干预 持续时间	干预方式		结局指标及 评定时间
				T	C		T	C	
Berndt 等[13]	纳入:8 岁～18 岁的 1 型糖尿病病人;疾病诊断至少 6 个月;接受 ICT or CSII 治疗。排除:缺乏阅读和书写技能;合并其他并发症。失访率为 0	T:12.9±2.0 C:13.2±2.9	T:21/13 C:20/14	34	34	3 个月	参与者每天将糖尿病相关数据发送到平台 Mobil Diab,研究团队中的 7 个医务人员使用 APP 分析数据,并提供反馈	常规治疗	结局指标:HbA1c、生活质量(DQOLY 量表)、家庭冲突量表、自我效能、儿童行为清单等。评定时间:基线、3 个月
Petrovski 等[14]	纳入:14 岁～23 岁的 1 型糖尿病的儿童和青少年。未报告失访率	T:17.4±2.4 C:16.9±2.7	T:12/15 C:13/16	27	29	12 个月	病人使用 Carelink 上传监测的糖尿病相关数据,专家通过 Skype 和 Facebook 给予反馈和干预措施	标准的医疗护理方案	结局指标:HbA1c、急性并发症、胰岛素使用量、体重改变等。评定时间:基线、12 个月
Hanberger 等[15]	纳入:0 岁～18 岁的诊断为 1 型糖尿病的病人,在 SWEDIABKIDS 登记注册、两个诊所就诊的病人。失访率 1.1%	T:13.2±3.7 C:13.3±3.7	T:48/52 C:49/51	100	100	1 年	病人通过网络平台 Diabit Web 2.0,可以和健康专家、同龄人进行交流;平台还包括糖尿病相关知识和社交功能	常规治疗和护理	结局指标:HbA1c、生活质量(DQOLY 量表)、严重低血糖的发生率等。评定时间:基线、12 个月
Harris 等[16]	纳入:12 岁～19 岁的 1 型糖尿病病人;疾病诊断>1 年;血糖控制不良(HbA1c≥9.0%)。排除:有精神障碍或其他精神疾病史病人。失访率 21%	T:14.94±1.77 C:15.04±1.79	T:29/17 C:26/18	46	44	12 周	治疗专家按照手册要求,通过 Skype 网络电话为糖尿病病人提供行为家庭系统治疗,共 10 期,共 1.0 h～1.5 h	治疗专家通过临床访视,为糖尿病病人提供行为家庭系统治疗	结局指标:HbA1c、糖尿病自我管理(DSMP 量表)等。评定时间:基线、12 周
Izquierdo 等[17]	纳入:5 岁～14 岁的 1 型糖尿病儿童(从幼稚园到 8 年级)。未报告失访率	T:9.74±2.18 C:10.56±2.50	未报告	23	18	1 年	常规护理+远程医疗干预:病人通过远程系统与糖尿病中心交流;IT 协调员亲自辅导学校护士和糖尿病中心执业培训 1 次	常规护理:每 3 个月到糖尿病中心复查 1 次;按需通过电话跟学校护士和父母交流;糖尿病中心的员工每年会对学校护士培训 1 次	结局指标:HbA1c、糖尿病儿童生活质量、满意度调查等。评定时间:基线、3 个月、6 个月、9 个月、12 个月
任恒杰等[18]	纳入:11 岁～16 岁的 1 型糖尿病病人;疾病诊断超过 6 个月;具备基本的语言沟通能力,能阅读和理解中文;能够在家里、医院或者社区上网。排除:病情危重者;意识不清楚或者有严重并发症者。失访率为 0	未报告	未报告	50	50	18 个月	网络心理教育:在医院主页上创建糖尿病专题讲座版块,课程结束 20 d 左右研究小组成员进行上门随访,对青少年病人实施心理干预时也要鼓励家属积极配合,随访人员访视期间也要对家属如何配合给予具体的建议	常规健康管理:只发放糖尿病知识宣传册,由 1 型糖尿病青少年和家属自己学习	结局指标:HbA1c、压力知觉量表、青少年生存质量测定量表、1 型糖尿病青少年自我管理量表。评定时间:基线、18 个月

注:T 为试验组,C 为对照组。DKA 为糖尿病酮症酸中毒;ICT 为传统胰岛素注射,CSII 为胰岛素泵。

2.3 纳入研究的方法学质量　根据 Cochrane handbook(5.1.0 2011)评价标准对纳入文献进行质量评价及分级,其中 3 项研究方法学评价质量较高,为 A 级,其余 11 项研究质量评价中等,为 B 级,详见表 2。

表 2 纳入研究的方法学质量

纳入研究	随机序列	分配隐藏	对参与者和实施者的盲法	对结局测量者的盲法	不完全数据报告	选择性发表	其他	总体评价
Lawsona 等[5]	低风险	低风险	低风险(单盲)	低风险	低风险	低风险	低风险	A 级
Franklin 等[6]	低风险	低风险	风险未知	风险未知	低风险	低风险	低风险	B 级
Rami 等[7]	风险未知	风险未知	风险未知	风险未知	风险未知	低风险	低风险	B 级
Nunn 等[8]	低风险	风险未知	风险未知	风险未知	低风险	低风险	低风险	B 级
Newton 等[9]	风险未知	风险未知	风险未知	低风险	低风险	低风险	低风险	B 级
Mulvaney 等[10]	低风险	低风险	风险未知	风险未知	风险未知	低风险	低风险	B 级
Landau 等[11]	低风险	低风险	风险未知	风险未知	低风险	低风险	低风险	B 级
Newton 等[12]	低风险	风险未知	风险未知	风险未知	低风险	低风险	低风险	B 级
Berndt 等[13]	风险未知	风险未知	风险未知	风险未知	低风险	低风险	低风险	B 级
Petrovski 等[14]	风险未知	风险未知	风险未知	风险未知	风险未知	低风险	低风险	B 级
Hanberger 等[15]	低风险	低风险	低风险	低风险	低风险	低风险	低风险	A 级
Harris 等[16]	低风险	低风险	低风险	低风险	低风险	低风险	低风险	A 级
Izquierdo 等[17]	低风险	风险未知	风险未知	风险未知	风险未知	低风险	低风险	B 级
任恒杰等[18]	风险未知	风险未知	风险未知	风险未知	低风险	低风险	低风险	B 级

2.4 Meta 分析结果

2.4.1 网络、手机对 1 型糖尿病儿童和青少年血糖控制的影响

共有 12 项研究将 Hb1Ac 作为结局指标评价网络和手机等信息技术对糖尿病病人血糖控制的影

响，对 12 项研究结果进行效果合并，同质性检验，$P=0.52$，$I^2=0\%$，Meta 分析结果显示网络和手机等信息技术对 1 型糖尿病儿童及青少年血糖控制没有影响[WMD＝－0.09，95%CI(－0.21，0.02)，$P=0.12$]。见图 1。

Study or Subgroup	试验组 Mean	SD	Total	对照组 Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Berndt 2014	8.1	1.1	34	8	1.3	34	4.0%	0.10 [-0.47, 0.67]
Franklin 2006	10.1	1.7	33	10.3	1.7	27	1.8%	-0.20 [-1.06, 0.66]
Hanberger 2013	6.7	1.2	100	6.7	1.2	100	12.0%	0.00 [-0.33, 0.33]
Harris 2015	10.4	1.66	46	10.45	2.05	44	2.2%	-0.05 [-0.82, 0.72]
Landau 2012	8.5	1.4	36	8.4	1.1	34	3.8%	0.10 [-0.49, 0.69]
Lawson 2005	9.4	0.3	23	9.6	0.3	23	44.1%	-0.20 [-0.37, -0.03]
Mulvaney 2010	9.1	1.8	34	8.5	1.3	18	1.8%	0.60 [-0.25, 1.45]
Newton 2009	8.25	0.63	38	8.48	0.69	40	15.4%	-0.23 [-0.52, 0.06]
Nunn 2006	8.85	1.29	60	8.82	1.1	63	7.4%	0.03 [-0.39, 0.45]
Petrovski 2015	6.4	1.6	27	6.6	1.5	29	2.0%	-0.20 [-1.01, 0.61]
Rami 2006	9.2	1.3	18	8.85	1.1	18	2.1%	0.35 [-0.44, 1.14]
任恒杰 2014	8.74	1.85	50	8.32	1.37	50	3.3%	0.42 [-0.22, 1.06]
Total (95% CI)			**499**			**480**	**100.0%**	**-0.09 [-0.21, 0.02]**

Heterogeneity: $\chi^2=10.15$, $df=11$ ($P=0.52$); $I^2=0\%$
Test for overall effect: $Z=1.54$ ($P=0.12$)

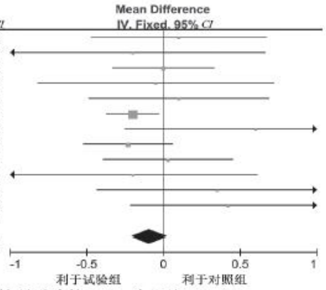

图 1　网络、手机对 1 型糖尿病儿童和青少年血糖控制影响的 Meta 分析结果

纳入的 12 项研究中，9 项通过网络进行干预，3 项通过手机短信和电话干预，因此评价网络和手机分别对 1 型糖尿病儿童及青少年血糖控制的影响。对网络干预进行亚组分析，结果显示：同质性检验，$P=0.84$，$I^2=0\%$，Meta 分析结果显示网络对1型糖尿病儿童及青少年血糖控制没有影响[WMD＝0.09，95%CI(－0.11，0.29)，$P=0.35$]。见图2。对手机干预进行亚组分析，结果显示：同质性检验，$P=0.58$，$I^2=0\%$，Meta分析结果显示手机干预使1型糖尿病儿童及青少年血糖控制不良，差异有统计学意义[WMD＝－0.18，95%CI(－0.32，－0.04)，$P=0.01$]。见图 3。

Study or Subgroup	试验组 Mean	SD	Total	对照组 Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Berndt 2014	8.1	1.1	34	8	1.3	34	12.2%	0.10 [-0.47, 0.67]
Franklin 2006	10.1	1.7	33	10.3	1.7	27	5.4%	-0.20 [-1.06, 0.66]
Hanberger 2013	6.7	1.2	100	6.7	1.2	100	36.2%	0.00 [-0.33, 0.33]
Harris 2015	10.4	1.66	46	10.45	2.05	44	6.7%	-0.05 [-0.82, 0.72]
Landau 2012	8.5	1.4	36	8.4	1.1	34	11.6%	0.10 [-0.49, 0.69]
Mulvaney 2010	9.1	1.8	34	8.5	1.3	18	5.5%	0.60 [-0.25, 1.45]
Petrovski 2015	6.4	1.6	27	6.6	1.5	29	6.1%	-0.20 [-1.01, 0.61]
Rami 2006	9.2	1.3	18	8.85	1.1	18	6.5%	0.35 [-0.44, 1.14]
任恒杰 2014	8.74	1.85	50	8.32	1.37	50	9.8%	0.42 [-0.22, 1.06]
Total (95% CI)			**378**			**354**	**100.0%**	**0.09 [-0.11, 0.29]**

Heterogeneity: $\chi^2=4.15$, $df=8$ ($P=0.84$); $I^2=0\%$
Test for overall effect: $Z=0.93$ ($P=0.35$)

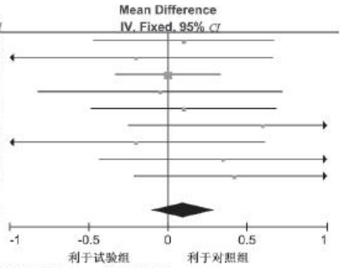

图 2　网络对 1 型糖尿病儿童和青少年血糖控制影响的 Meta 分析结果

Study or Subgroup	试验组 Mean	SD	Total	对照组 Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Lawson 2005	9.4	0.3	23	9.6	0.3	23	65.9%	-0.20 [-0.37, -0.03]
Newton 2009	8.25	0.63	38	8.48	0.69	40	23.1%	-0.23 [-0.52, 0.06]
Nunn 2006	8.85	1.29	60	8.82	1.1	63	11.0%	0.03 [-0.39, 0.45]
Total (95% CI)			**121**			**126**	**100.0%**	**-0.18 [-0.32, -0.04]**

Heterogeneity: $\chi^2=1.10$, $df=2$ ($P=0.58$); $I^2=0\%$
Test for overall effect: $Z=2.53$ ($P=0.01$)

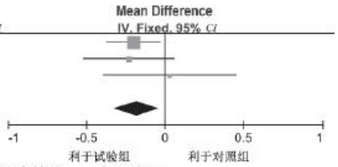

图 3　手机对 1 型糖尿病儿童和青少年血糖控制影响的 Meta 分析结果

2.4.2　网络、手机等对 1 型糖尿病儿童和青少年胰岛素使用量的影响　共有4项研究将胰岛素使用量作为结局指标，对其进行效果合并。同质性检验，$P=0.02$，$I^2=68\%$，采用随机效应模型，Meta 分析结果显示网络和手机等技术对 1 型糖尿病儿童及青少年胰岛素使用量没有影响[WMD＝0.06，95%CI(－0.06，0.19)，$P=0.32$]。见图 4。

Study or Subgroup	试验组 Mean	SD	Total	对照组 Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Berndt 2014	47	24.4	34	46.3	17.8	34	0.0%	0.70 [-9.45, 10.85]
Franklin 2006	4.3	5.4	33	2	1.1	27	0.4%	2.30 [0.41, 4.19]
Lawson 2005	1.26	0.08	23	1.25	0.07	23	53.4%	0.01 [-0.03, 0.05]
Newton 2009	1.215	0.21	38	1.113	0.14	40	46.2%	0.10 [0.02, 0.18]
Total (95% CI)			**128**			**124**	**100.0%**	**0.06 [-0.06, 0.19]**

Heterogeneity: $\tau^2=0.01$; $\chi^2=9.51$, $df=3$ ($P=0.02$); $I^2=68\%$
Test for overall effect: $Z=0.99$ ($P=0.32$)

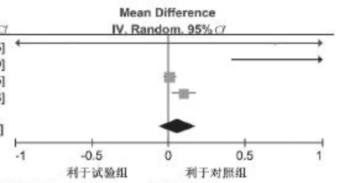

图 4　网络、手机等对 1 型糖尿病儿童和青少年胰岛素使用量影响的 Meta 分析结果

2.4.3　描述性研究　对无法进行 Meta 分析的指标进行描述性分析。Landau[11,17]等调查显示：大部分儿

童及青少年认为网络平台对糖尿病管理是有效的,表示会继续使用网络平台服务;Rami 等[7]研究结果略有不同,部分病人认为登陆网络系统和传输数据增加了额外的工作量,很耗时。但这 3 项研究都是通过研究团队自制满意度量表进行调查,未见信效度检验的相关指标,因此其结论还有待进一步验证。此外,Rami 等[7]研究还发现:通过网络干预,学生因为糖尿病相关问题紧急咨询学校护士的时间显著减少,急诊使用率和再入院率减低,6 个月内试验组病人的情绪功能显著提高;但因设计相关指标的研究少,无法进行效果合并,因此其结果的有效性有待验证。

3　讨论

3.1　纳入研究的方法学质量评价　纳入的14篇文献中,有9篇(64.29%)报道了随机分组方法,6篇(42.86%)报道了分配隐藏的方案;仅有 3 篇(21.43%)实施了对参与者、实施中和结局测量者的盲法;仅有 4 篇文献未报道退出和失访情况;所有研究的试验组和对照组都比较基线资料,且基线均具有可比性。

3.2　网络、手机等信息技术对 1 型糖尿病儿童和青少年血糖管理的影响　与 2 型糖尿病病人相比,1 型糖尿病儿童和青少年的自我管理能力较差,这与多方面的因素有关,主要包括:胰岛素敏感性的变化、由生长发育引起的青少年时期的生理和心理问题、自我管理能力欠缺、认知层面上的学校生活和自我认识下降等[19]。网络和手机等现代信息技术作为评估和干预工具,能针对特定年龄和发展阶段的病人,有利于互动,易于更新,越来越多地被运用到糖尿病病人的管理中,尤其是儿童和青少年。Whittemore 等[20]研究认为基于网络平台的干预有利于提高 1 型糖尿病病人的生活质量和自我管理能力。Frøisland 等[21]研究发现:智能手机作为可视化工具,能帮助年轻人更好地理解糖尿病,加强饮食控制,增强自我管理能力。这与本研究结果存在一定矛盾。本研究结果显示:网络和手机等不能帮助 1 型糖尿病儿童和青少年有效地控制血糖,不能减少胰岛素使用量,这与理论上的设想相违背。分析其原因:一方面与信息技术本身的特点有关,原因是专家不能与每位病人进行面对面交流,病人的依从性较差,网络及手机干预应重视被研究对象年龄特征和需求;现代信息技术干预的手段多样,尤其是网络,无线通讯(GPRS)信号、平台的容量、界面是否友好、流程是否优化都直接影响病人的使用体验和满意度。另一方面与纳入研究的质量直接相关,目前探索基于网络和手机等技术对 1 型糖尿病儿童和青少年影响的文献多为质性研究,本研究纳入的随机对照试验仅有 3 项质量评价为 A 级,文献质量有待提高;且是否使用信息技术是研究分组的依据,很难对病人及实施者实行盲法,未能实施盲法可能导致研究结果偏倚;相关研究的结局指标差异较大,每项指标的测量工具也不尽相同,研究结论能否外延还有待进一步探讨;纳入研究的持续时间为 7 周至 18 个月,多数研究持续时间较短,但 1 型糖尿病是长期慢性代谢性疾病,较少研究探索现代信息技术对 1 型糖尿病病人的长期影响。因此,对上述结果应谨慎对待。

4　结论

网络、手机、电子设备等现代信息技术不能帮助 1 型糖尿病儿童和青少年有效控制血糖,减少胰岛素使用量,这与大多数质性研究结果不一致。鉴于本研究纳入研究的结局指标异质性较大,文献质量不高,样本量较小,因此,尚需要设计合理、具有客观统一结局指标的大样本、高质量随机对照试验研究,以获得更稳定、可靠的证据。

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Appendix 2: PRISMA checklist for the systematic review (in chapter 2)

Section/topic	#	Checklist item	Page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	35
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	35-36
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	36-37
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	37
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Not avaliable
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	38-39
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	38
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	38
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	40
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	40

Section/topic	#	Checklist item	Page #
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	38-40
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	40
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	39
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis.	40
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	40
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	40
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	40-42
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Appendi x 3;
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12)	44-47
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	48-55
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	48-55
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	44-47
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	48-49

Section/topic	#	Checklist item	Page #
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	55-57
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	57-58
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	59
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Not available

Appendix 3: Characteristics of included studies in systematic review-chapter 2

Author	Inclusion/exclusion criteria	Intervention		Time to follow up	Measurement tools	Main results
		Intervention group (T)	Control group (C)			
Berndt 2014 (Germany)	**Inclusion criteria**: 8-18-year children and teens; diagnosed with type 1 diabetes; with disease duration of at least half a year; following the intensified conventional insulin therapy (ICT) or continuous subcutaneous insulin infusion (CSII) therapy; should have reading and writing skills; **Exclusion criteria:** Those notified with other diseases during the initial examination, as well as those with weaknesses in reading and writing were not included in the test phase; Sample size: T: n=34 C: n=34	**Mobile application "Mobil Diab":** patients in the intervention group used the "Mobil Diab" successively for 4 weeks. During this period of time, they sent their daily diabetes-related records to the central platform. These records included blood glucose values, nutrition and drugs information, which were recommended to upload at least 3 times a day. Mobility and sport-related information were also recorded. Seven members of the medical staff, including 2 diabetes specialists, 2 treating doctors, 2 nurses and 1 psychologist, used the web-based application to access and analyse data and provide feedback.	Conventional therapy without the use of telemedicine system;	4 w	**Objective outcomes:** Body weight, Body-mass Index (BMI) , HbA1c, Insulin dose; **Psychological outcomes:** Quality of life-Quality of Life for Youth Scale (DQOLY) ; Diabetes Self-Efficacy Scale;	1. A significant improvement in the "diabetes self-efficacy" domain was depicted in the intervention group. 2. In the control group, no significant change in the psychological parameters was observed; 3. Both the control and intervention cohorts demonstrated a reduction in HbA1c during the study period.
Franklin 2006 (UK)	Inclusion criteria: Paediatric patients attending clinics in Tayside, Scotland; aged between 8 and 18 years; had Type 1 diabetes for more than 1 year; were on conventional insulin therapy (CIT; two or three daily injections of premixed insulin); Exclusion criteria: Patients with serious social problems, severe learning difficulties and needle phobia were excluded; Sample size: T: n=32 C: n=27	Group 2: Sweet Talk intervention (a text-messaging system) + conventional insulin therapy: all patients allocated to the Sweet Talk intervention participated in goal setting at clinic visits. They were also given a card detailing the functions of the text-messaging service. The Sweet Talk is an automated, scheduled text-messaging system designed to offer regular support to patients with diabetes to optimize their self-management and control.	Group 1: Conventional insulin therapy.	12 m	**Primary outcomes:** HbA1c, self-efficacy for diabetes score ; diabetes knowledge score; the diabetes social support interview; **Secondary outcomes:** episodes of DKA; severe hypoglycaemia; body mass index; and health service utilization (number of clinic visits and emergency hotline contacts);	1. Glycaemic control significantly improved in patients in group 2. 2. Patients who received the Sweet Talk intervention scored significantly higher on self-efficacy for diabetes than patients without Sweet Talk and improved self-reported adherence score. 3. Sweet Talk increased patients' perception of the quantity of support from the diabetes team.

Author	Inclusion/exclusion criteria	Intervention		Time to follow up	Measurement tools	Main results
		Intervention group (T)	Control group (C)			
Freeman 2013 (Portland)	**Inclusion criteria**: Youth between the ages of 12 and 19 years (at enrollment) with T1DM; was in poor metabolic control (HbA1c ≥ 9.0%); at least one parent/legal guardian were recruited; Sample size: T: n=32 C: n=39	**Skype intervention:** participants received up to 10 sessions lasting 1 to 1.5 h of BFST-D within a 12-week time frame either via Skype. Therapists followed the behavioral family systems therapy for diabetes (BFST-D) manual. Therapists included one psychology intern and two doctoral level therapists. All therapists received preparatory training and weekly supervision.	Traditional clinic-based visits	12w	Working Alliance Inventory (WAI)	There were no significant differences in WAI scores across those receiving BFST-D via Skype versus in-clinic.
Goyal 2017 (Canada)	**Inclusion criteria**: had a diagnosis of type 1 diabetes for 1 year or more; between the ages of 11 and 16 years, inclusive, at the time of enrollment; had been followed at the current clinic for at least 6 months; had 2 of their 3 most recent HbA1c readings (including the day of enrollment) between 8.0% and 10.5%; **Exclusion criteria:** participants were excluded if they did not fluently speak and understand English. Sample size: T: n=46 C: n=45	**A Mobile App:** those allocated to the intervention group received an iPhone 4S loaded with *bant*, which was diabetes self-management app, including wireless blood glucose reading transfer, out-of-range blood glucose trend alerts, coaching around out-of-range trend causes and fixes, and a point-based incentive system.	**Control group:** they did not receive any study-related hardware from the research team.	12 m	**Primary outcomes:** HbA1c; **Secondary outcomes:** the frequency of mild and severe hypoglycemic events; the average number of daily SMBG (Self-Monitoring of Blood Glucose); the number of self-initiated adjustments; the Diabetes Quality of Life for Youth (DQOLY) questionnaire;	1. There was no significant difference in HbA1c between the intervention and control groups among 12 months. 2. There was a significant relationship found between increased SMBG and improved HbA1c in the intervention group, which strengthened at 9-month and 12-month visits.

Author	Inclusion/exclusion criteria	Intervention		Time to follow up	Measurement tools	Main results
		Intervention group (T)	Control group (C)			
Han 2015 (USA)	**Inclusion criteria**: be 10-17 years of age; have been diagnosed with TID for over 1 year; have the most recent HbA1c test result between 7.5% and 11%; have his or her own cell phone; have an unlimited SMS text plan; be able to read English at a 5th grade level; Sample size: T: n=10 C: n=10	**Text-Messaging:** the text messaging system contained three main components: (1) text messaging management for sending and receiving text messages; (2) Web-based dashboard for reviewing the text message responses by diabetes educators and providers; (3) visualization printout from the dashboard.	**Control group**	26w	HbA1c, the Problem Areas in Diabetes (PAID) questionnaire; the Diabetes Quality of Life for Youth (DQOLY) questionnaire; semi-structured interviews about the adolescents' experiences using the text-messaging system;	1. There were no significant differences in HbA1c changes between the groups. 2. It reported a significant improvement in some aspects of QOL in the SK group (symptom and knowledge intervention). 3. Text help improve awareness of symptoms, and remind adolescents to check glucose.
Hanberger 2013 (Sweden)	**Inclusion criteria**: diagnosed with type 1 diabetes children; aged 0-18 years; registered in the Swedish pediatric diabetes quality registry, SWEDIABKIDS; belonging to the geographic population of the two pediatric clinics in Linköping and Jönköping; Sample size: T: n=233 C: n=261	**A Web 2.0 Portal:** developed in collaboration with patients, parents, and practitioners; offered self-directed communication with health professionals, interaction with peers, and access to information. It contained specific diabetes-related information on 13 main topics, and social networking functions such as a storyboard, a simple blog module, and discussion board modules.	**Control group**	12m	**The clinical variables:** HbA1c; severe hypoglycemia; self-controls of blood glucose; **Questionnaires:** the DISABKIDS chronic-generic module and the diabetes-specific module; the Quality from the Patients' Perspective (QPP) questionnaire; the Swedish Diabetes Empowerment Scale, short version (SWE-DES-SF-10);	No differences were found after study year 1 between the intervention and control group among adolescents regarding the outcome variables (HRQOL, empowerment, perception of quality of care regarding information, HbA1c, severe hypoglycemia, frequency of blood glucose self-control)).

Author	Inclusion/exclusion criteria	Intervention		Time to follow up	Measurement tools	Main results
		Intervention group (T)	Control group (C)			
Harris 2015 (Portland)	**Inclusion criteria**: a diagnosis of type 1 diabetes of at least 1 year duration; age 12 to 19 years; and suboptimal glycemic control (HbA1c≥9.0% or ≥74.9 mmol/mol); Adolescents needed to reside with a primary caretaker, intend to reside with the primary caretaker for the duration of the study (7 months), have no history of mental retardation or other mental health condition and not have an uncontrolled medical condition (e.g., cystic fibrosis). Sample size: T: n=29 C: n=35	**Internet videoconferencing (Skype):** Participants received up to 10 sessions of behavioral family systems therapy for Diabetes (BFST-D) that lasted 1-1.5 h each. Therapists and families communicated to establish regular meeting times, and a research assistant provided reminder calls for upcoming appointments approximately 2 days before the appointment. All participants continued to receive regular medical care by their diabetes care providers during the course of the study.	**Clinic group**	7m	HbA1c, the Diabetes Self-Management Profile-Diabetes (DSMP)	1. There were no between-group differences in adherence and glycemic control. 2. However, significant improvements in Youth-DSMP scores occurred after the intervention and that the improvements were maintained at the 3-month follow-up. 3. Significant improvements in glycemic control also occurred after intervention, which maintained at 3 months.
Izquierdo 2009 (USA)	**Inclusion criteria**: children with type 1 diabetes aged 5 to 14 years (grades kindergarten through eighth); Sample size: T: n=23 C: n=18	**School-Centered Telemedicine intervention:** a school telemedicine system with a centrally managed internet-based portal to facilitate communication between the school and diabetes center; The launch of a prescheduled regular monthly meeting (10-20 minutes) between the school nurse, student with or without a parent, and diabetes nurse practitioner was usually accomplished. The application portal also made available an educational curriculums with 18 short modules.	**Usual care:** visits to the diabetes center every 3 months	12m	**Primary outcomes:** HbA1c; **Secondary outcomes:** the Pediatric Diabetes Quality of Life Generic Module; the Pediatric Diabetes Quality of Life (PedsQL) Diabetes Module;	1. A1c values increased at 6 months in the usual care group (not significant) but decreased significantly in the telemedicine group. 2. Urgent visits to the school nurses for diabetes-related problems and urgent calls to the diabetes center decreased significantly in the telemedicine group. 3. Pediatric QOL did not differ between groups after intervention.

Author	Inclusion/exclusion criteria	Intervention		Time to follow up	Measurement tools	Main results
		Intervention group (T)	Control group (C)			
Klee 2018 (Switzerland)	**Inclusion criteria**: 10 to 18 years of age with a diagnosis of type 1 diabetes (as defined by the American Diabetes Association) for at least 6 months; were either treated by pump therapy or multiple daily injections; **Exclusion criteria:** those who had previously used *Webdia*, or who did not have the necessary hardware to install the program, or who would not be able to use the program for another reason; Sample size: T: n=20 C: n=26	A patient-designed Do-It-Yourself mobile device App (*Webdia-group A*): participants can use *Webdia* as often as possible for a period of 3 months. Blood glucose values were reviewed every month by the diabetologists on a secure website, and suggestions for treatment adaptation were sent to the participants by e-mail. The content of the e-mail was standardized and always consisted of a comment about the glucose values and, if necessary, a suggestion to adjust the insulin regimen by changing the application's settings.	Control group (Group B)	3m	**Primary outcomes:** HbA1c; **Secondary outcomes:** the Diabetes QoL for Youth questionnaire; Hypoglycemic events; satisfaction of the participants;	1. There was no significant impact during the 3 months, however, the patients with HbA1c>8.0% at inclusion revealed a significant reduction in HbA1c after a 3-month use of *the App*. 2. The frequencies of patient-reported hypoglycemic events during the two last weeks of *the App* use versus usual care were not significantly different.
Landau 2012 (Israel)	**Inclusion criteria**: diagnosis of T1D, age between 11-20 years, disease duration of at least 6 months, willingness and consent to participate in the study and to maintain regular follow-up every 3 months as usual, no documented mental retardation; Sample size: T: n=36 C: n=34	**Internet-based blood glucose monitoring system:** The intervention group was instructed to report their self-monitoring blood glucose results weekly via *the Medtronics' Internet Web* site during the study period of 6 months and to inform the study coordinator by e-mail that an upload had been made. With patient permission, the study coordinator could then sign on to the Web site and view the data. A phone call response, including recommendations for changes in treatment, was conducted by the study coordinator following consultation with the physician. If a change in insulin dosage was required, or if glycemic control worsened, a member of the clinic staff contacted the parents by phone.	**The control group**	6m	**Primary outcomes:** HbA1c; **Secondary outcomes:** number of severe hypoglycemic episodes; number of DKA episodes; number of data upload sessions, the time the study coordinator spent in reviewing data and providing patients with feedback, number of visits in the diabetes clinics during the intervention period;	1. The number of patients who reached an HbA1c value of 7.5% or less was 10/36 in the intervention group and 5/34 in the control group at 6 months. 2. There was one episode of DKA and no episodes of severe hypoglycemia in the intervention group. 3. Most patients considered that the system was useful for diabetes management.

Author	Inclusion/exclusion criteria	Intervention		Time to follow up	Measurement tools	Main results
		Intervention group (T)	Control group (C)			
Lawson 2005 (Canada)	**Inclusion criteria**: Adolescents (13-17 year of age) with type 1 diabetes for at least 1 year; were receiving insulin twice or three daily; under poor metabolic control (HbA1c>8.5% over the previous 6 months); **Exclusion criteria:** Adolescents who had other chronic medical conditions were excluded, with the exception of treated hypothyroidism or asthma requiring oral glucocorticoids less than twice per year; Sample size: T: n=23 C: n=23	**Regular standardized telephone contact:** 6 months of weekly, standardized telephone contact with the adolescent was initiated by a diabetes nurse educator (DNE). The nurse would ask the adolescent for his/her blood sugar levels over the last week. The nurse would then discuss the blood sugar levels with the teenager and make recommendations regarding any necessary insulin-dose adjustments.	**Standard diabetes management:**	6m	**Primary outcomes:** HbA1c; **Secondary outcomes:** the Compliance with Diabetes Management Scale (CDMS) questionnaire; Diabetes Quality of Life Scale for Youth (DQOLY) questionnaire; Family Environment Scale (FES); Total daily insulin dose; body mass index (BMI); adverse events;	1. There were no significant differences in HbA1c in two groups. 2. There were no clinically important differences between the groups at 6 months follow-up in terms of quality of life, family functioning, insulin dose, or frequency of severe hypoglycemia. 3. At 6 months, there were slight differences in the adherence ratings between the groups with higher adherence in self-management reported by the telephone subjects.
Lehmkuhl 2010 (USA)	**Inclusion criteria**: youth between the ages of 9 and 17 years; diagnosis of T1DM for at least six months; an HbA1c greater than 9%; and the availability of a caregiver to accompany a participant to assessments; Sample size: T: n=18 C: n=14	**Telehealth Behavior Therapy:** each family was assigned to one therapist who provided all sessions. Sessions were conducted according to the manualized protocol using some principles from behavior family systems therapy. It included three weekly phone contacts over 12 weeks, lasting approximately 15-20 min each. Therapists spoke with both the child and the parent during each phone call. Self-care activities and reinforcing adaptive self-care (diabetes goals) and identifying potential barriers to management and education were discussed.	**Waitlist participants** had no contact with study therapists during the interim.	12w	A1cNow (a single-use, disposable monitor for the measurement of HbA1c in finger stick); the diabetes self-management profile (DSMP); The diabetes family behavior scale (DFBS) (children's perceptions);	1. Mean HbA1c scores reduced from 10.2% to 9.8%, however, there was no effect of group membership. 2. There was no significant effect of intervention on diabetes management behaviors and children's perceptions of family support related to type 1 diabetes management.

Author	Inclusion/exclusion criteria	Intervention		Time to follow up	Measurement tools	Main results
		Intervention group (T)	Control group (C)			
Mulvaney 2010 (USA)	**Inclusion criteria**: were 13-17 years; had Internet access; were diagnosed with type 1 diabetes for at least 6 months; spoke English; and had no disabilities that precluded understanding website content; Sample size: T: n=34 C: n=18	**Internet-based problem-solving self-management support:** A multidisciplinary team of diabetes professionals and young patients edited website content. During 11 weeks, six multimedia stories depicted psychosocial barriers to self-management and approaches to coping and problem solving. Participants were prompted twice to complete problem solving cycles for personal barriers to self-management.	Usual care	12w	A1c; the Diabetes Behavior Rating Scale; the Diabetes Problem Solving Behaviors scale;	1. The intervention group A1C remained constant but showed improvement relative to the control condition. 2. Problem solving improved insignificantly in the intervention group, however, self-management adherence significantly improved.
Newton 2009 (New Zealand)	**Inclusion criteria**: adolescents aged 11-18 years with type 1 diabetes; Sample size: T: n=35 C: n=39	**Pedometers and Text Messaging:** Participants wore an open pedometer every day for 12 weeks, with a goal of at least 10,000 steps/day. A pedometer can be opened by a participant to monitor and record the number of steps taken. Steps per day were recorded on a chart. Each week, participants received a motivational text message reminding them to wear a pedometer.	Standard care	12w	**Primary outcomes:** a 4-day step count; self-reported physical activity over 7 days; **Secondary outcomes:** A1C; blood pressure; BMI Z score; QOL; adherence;	1. At 12 weeks, there was no significant difference in change in activity measures between the groups. 2. Differences were also not significant at 12 weeks for A1C, BMI Z score, quality of life, and blood pressure.
Newton 2013 (USA)	**Inclusion criteria**: adolescents with 13-18 years of age; diagnosed with type 1 diabetes; to have Internet access at home; and to have experience with Internet chat rooms and discussion boards; **Exclusion criteria:** had been diagnosed with diabetes within 6 months or had changed insulin delivery methods to an insulin pump within the 6 weeks. Sample size: T: n=25 C: n=25	**The web site (''Diabetes Teen Talk''):** including three functions, blogs (creating their own blog, commenting on visible blog and goal setting and journal entries about the weekly topic entries), discussion forums (moderator hosted a chat session weekly) and a chat room (general discussion, diabetes-related scenarios discussion and open discussion);	**Standard medical care** as usual, with no participation on the website.	7w	The Diabetes Quality of Life for Youths; the Self-Efficacy of Diabetes Self-Management; Outcome Expectations of Diabetes Self-Management;	1. The control group reported higher positive outcome expectations of self-management than those in the interventional group. 2. There were no significant differences between groups on QOL, Self-Efficacy or Negative Outcome Expectations of self-management.

Author	Inclusion/exclusion criteria	Intervention		Time to follow up	Measurement tools	Main results
		Intervention group (T)	Control group (C)			
Nunn 2006 (Australia)	**Inclusion criteria**: been diagnosed more than 12 months previously, were older than 3 yr, and had a mean HbA1c level over the previous 6 months>8%. Sample size: T: n=60 C: n=63	**Scheduled telephone calls:** bimonthly phone calls lasting 15-30 min from the educator; The phone discussions covered three main topic areas. The first was the current insulin, carbohydrate intake, and blood glucose values. Second, current events, which may impact on diabetes management, were discussed. Finally, an educational program was conducted over the phone using provided written material and illustrations.	**Subjects in the control group** attended clinics normally	7m	**Principle outcome:** HbA1c; **Secondary outcomes:** hospitalization; Test of Diabetes Knowledge (mTDK); compliance; the Strengths and Difficulties Questionnaire (P11-17) (SDQ); and Indicators of Social and Family Functioning (ISAFF);	1. There was a significant increase in HbA1c level in the intervention group. 2. There was no statistical difference in the mTDK throughout the study for patient’s scores. 3. There was no significant difference between the SDQ subscores in the two groups.
Rami 2006 (Austria)	**Inclusion criteria**: HbA1c≥8% (normal range: 4-6%), a duration of disease>1 year, an age between 10-19 years, and the willingness and consent to participate in our study and to attend follow up visits every 3 months. Sample size: T: n=18 C: n=18	**A telemedical (TM) support program (TM-PD group):** VIE-DIAB was a telemedical system and program, which was developed to try to improve glycemic control. The group started using the VIE-DIAB system and weekly advice for 3 months, and then switched to the routine scheme with a daily paper diary.	**PD-TM group:** This group started with a daily paper diary	3m	HbA1c; adverse events, such as severe hypoglycemia or diabetic ketoacidosis; BMI (kg/m2) ; insulin dosage (IE/kg/d);	1. HbA1c reduced during the TM phase but increased again during the PD phase. 2. Severe hypoglycemia, DKA, BMI and insulin dosage were not different between the two groups.
Ren 2014 (China)	**Inclusion criteria**: were diagnosed with type 1 diabetes more than 6 months; can read and understand Chinese; have access to internet at home, or in the hospital or community; aged 11-16 years; **Inclusion criteria**: the disease was in a critical condition; was subconscious or had severe complications; was reluctant to attend the research; Sample size: T: n=50 C: n=50	**Internet-based psychological education:** A board of official website was built to introduce diabetes knowledge. At the beginning of a month, diabetes doctors or nurses were invited to give lectures to patients and parents, which was also recorded and uploaded on the website for patients to watch repeatedly. The research team also provided home visit to know the assessment of patients on the lectures every month.	**Control group:** patients and parents were given some leaflet to read by themselves.	18m	HbA1c; Perceived Stress Scale; the Pediatric quality of life Inventory measurement model; Self-report measure of self-management of type 1 diabetes for adolescents;	1. After 18 months, HbA1c reduced significantly in the intervention group. 2. There were significant tion effects found in the intervention group on perceived stress, quality of life and self-management.

Author	Inclusion/exclusion criteria	Intervention		Time to follow up	Measurement tools	Main results
		Intervention group (T)	Control group (C)			
Stanger 2018 (USA)	**Inclusion criteria**: aged 13-17, average HbA1c ≥8% for past 6 months, most recent HbA1c ≥8%, type 1 diabetes duration >18 months, at least one parent/guardian participant living with the adolescent, and a computer with Internet at home; **Exclusion criteria:** pregnancy, severe medical or psychiatric illness, plans to leave within 12 months, and concurrent counseling on diabetes regimen adherence. Sample size: T: n=30 C: n=31	**A Web-Delivered Multicomponent Intervention:** *WebRx* was an online Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant web conference system. The intervention included incentives, brief motivational interviewing/cognitive behavioral therapy and parent contingency contracting sessions, and working memory training all delivered over the internet.	**Usual care:** standard treatment	12m	**Principle outcome:** self-monitoring of blood glucose frequency; **Secondary outcomes:** the Revised Parental Monitoring of Diabetes Care questionnaire; the Revised-Diabetes Family Conflict Scale; a computerized Stroop Color-Word test; HbA1c;	1. Between-group differences were observed for parent monitoring of the adolescent's glucometer use, and visual spatial working memory, however, there is a lack of significant effect at 12 months. 2. There were significant differences favoring *WebRx* at 6 and 12 months on HbA1c and family conflict.
Zhang 2018 (USA)	**Inclusion criteria**: were 13-17 years old, diagnosed with T1D>12 months, and HbA1c 7.5%-12.0% (59-108 mmol/mol); Sample size: T: n=24 C: n=24	**A Text-Messaging PA (promoting positive affect) Intervention:** Adolescents in the PA group received 4-5 text messages/week over the 8-week intervention period. Separate message banks were developed for girls and boys with the highest ranked Mood Booster messages, which were sent 2-3 times/week. Caregivers in the PA group were sent weekly reminders to give positive messages to their adolescents.	**Usual care**	8w	Adherence measured by the frequency of BGM (average number of checks/day over the previous 30 days); the self-care inventory(SCI); HbA1c;	1. There were no significant effects of the intervention (PA vs. Education) on HbA1c, BGM (blood glucose monitoring), or adherence. 2. There was an improvement in BGM over time, but it was not statistically significant.
Chatzakis 2019 (Greece)	**Inclusion criteria**: Children and adolescents (7 - 17 years) with T1DM; owned an smartphone and were familiar with its use; satisfactory knowledge of carbohydrates and lipids counting acquired from previous training; **Exclusion criteria:** Use of another medical application for T1DM in the previous 3 months; lack of capacity of reading Greek; Sample size: T: n=40 C: n=40	**A mobile application "Euglyca® application"** contained a data base of 7000 foods and food products; The app calculated the amount of carbohydrates and lipids in a meal, provided a structured approach for the calculation of the bolus insulin dose, and the level of physical activity patients needed.	**Usual care:** patients calculated bolus insulin dose they were injected;	12m	HbA1c; percentages of hypoglycemias, hyperglycemias and normoglycemias; Diabetes Treatment Satisfaction questionnaire (DTSQ);	Children and adolescents in the intervention group had a significantly decrease in HbA1c values and increase in percentages of normoglycemias and treatment satisfaction scores, in comparison to children and adolescents in the C group.

Author	Inclusion/exclusion criteria	Intervention		Time to follow up	Measurement tools	Main results
		Intervention group (T)	Control group (C)			
Ebrahimpour 2015 (Iran)	**Inclusion criteria**: children between 3-12 year with T1DM, administering insulin by mothers by use of syringe or insulin pen, as well as observed distress in children, or what their mothers' stated as children's distress while injecting insulin, willing to participate in the study, no morbidity of specific mental and physical disorders, and home availability of computer. **Exclusion criteria:** uncooperative mothers or children, those had acute recent problems (acute illnesses, hospitalization, and death of close family members); Sample size: T: n=15 C: n=15	**An interactive computer game "Koodak-e-Tavana":** included seven parts including: 1) paired game (familiarize with equipments needed for insulin injection); 2) puzzle game (observing another child that has no fear of insulin injection); 3) question and answer game (some educational topics on insulin injection); 4) insulin kit game (preparing insulin kit); 5) painting room; 6) story game (narration a short story); 7) insulin injection-room (creating a simulated environment for insulin injection); Adolescents were asked to play at least once a week;	**Usual care:** no special intervention;	2w	Observational Scale of Behavioral Distress-Revised (OSBD-R);	1. There were signification decreases in distress over time in the study group; 2. Diabetic children who played with computer game were significantly lower behavioral distress during insulin injection than the control group;
Rafeezadeh 2019 (Iran)	**Inclusion criteria**: 1) aged 8-12 years, 2) no family history of diabetes, 3) having parents or legal guardians, 4) lack of any other disorders, such as learning difficulties, 5) lack of participation in any educational programs on diabetes self-management over the last 6 months, 6) literacy ability of parents and children, and 7) the existence of a desktop computer or a laptop in families; **Exclusion criteria:** unwilling to continue the study; played the video game less than an hour or more than four hours a week; and those children whose one of their close relatives died during the research; Sample size: T: n=34 C: n=34	**An educational interactive video game** included diet, exercise, medication, hypo/hyperglycemia symptoms, preventive care, care for injuries, and general health. Each stage of the game began with a short educational clip on a special self-care topic. Afterward, the child was given the opportunity to play the game and make choices. To pass each stage and to enter into the next one, a certain amount of positive points would have to be achieved over time. Children in the intervention group were requested to play the video game for 12 weeks and at least one hour and a maximum of four hours a week.	**Control group:** no mention	3m	HbA1c; Diet-Exercise Regimen Adherence Questionnaire (researcher designed)	1. Adherence to a diet regimen and an exercise regimen was significantly higher in the intervention group; no difference was found in adherence of medication; 2. It showed no significant difference between groups regarding the mean HbA1c level;

Appendix 4: Ethic approval from the University of Hull (FHS122)

UNIVERSITY OF HULL

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United Kingdom
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w: www.hull.ac.uk

PRIVATE AND CONFIDENTIAL
Xiaolei Zhao
Faculty of Health Sciences
University of Hull
Via email

1st April 2019

Dear Xiaolei

REF FHS122 - Development and feasibility test of a web-based diabetes education intervention in adolescents (10-19 years old) with Type 1 Diabetes Mellitus

Thank you for your responses to the points raised by the Faculty of Health Sciences Research Ethics Committee.

Given the information you have provided I confirm approval by Chair's action.

Please refer to the Research Ethics Committee web page for reporting requirements in the event of any amendments to your study.

I wish you every success with your study.

Yours sincerely

Professor Liz Walker
Chair, FHS Research Ethics Committee

UNIVERSITY OF HULL

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Appendix 5: Ethic approval from the hospital in Luzhou (KY2019020)

项目伦理批准确认函

兹证明，由我院护理职工赵小磊（现在英国赫尔大学就读博士学位）主持的项目“基于网络的 1 型青少年（10-19 岁）糖尿病患者教育的可行性研究”，申请号为 KY2019020，已通过临床试验伦理委员会（西南医科大学附属医院临床试验伦理委员会）审查。研究人员务必严格按照提交的研究计划实施。

西南医科大学附属医院临床试验伦理委员会

2019-04-29

Ethics approval confirmation

This letter is to certify that the nursing project “Development and feasibility testing of a web-based diabetes education intervention in adolescents (10-19 years old) with Type 1 Diabetes Mellitus” is approved by the Ethics Committee of the Affiliated Hospital of Southwest Medical University in Luzhou, China. The primary investigator is Xiaolei Zhao who is a nurse in our hospital and studying in the University of Hull as a PhD student. Application number of the project is KY2019020. The investigator should follow what mentioned in the research proposal and applications forms.

Ethics Committee of the Affiliated Hospital of Southwest Medical University

29/4/2019

Appendix 6: Amended ethic approval from the University of Hull (FHS122)

UNIVERSITY OF HULL

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PRIVATE AND CONFIDENTIAL
Xiaolei Zhao
Faculty of Health Sciences
University of Hull
Via email

12 June 2019

Dear Xiaolei

REF FHS122 – Development and feasibility testing of a web-based diabetes education intervention in adolescents (10-19 years) with Type 1 Diabetes Mellitus (T1DM)
Amendment 11.6.2019

Thank you for submitting your Form C: Notice of Substantial Amendment to the Faculty of Health Sciences Research Ethics Committee.

Given the information you have provided I confirm approval by Chair's action.

Please refer to the Research Ethics Committee web page for reporting requirements in the event of any further amendments to your study.

I wish you every success with your study.

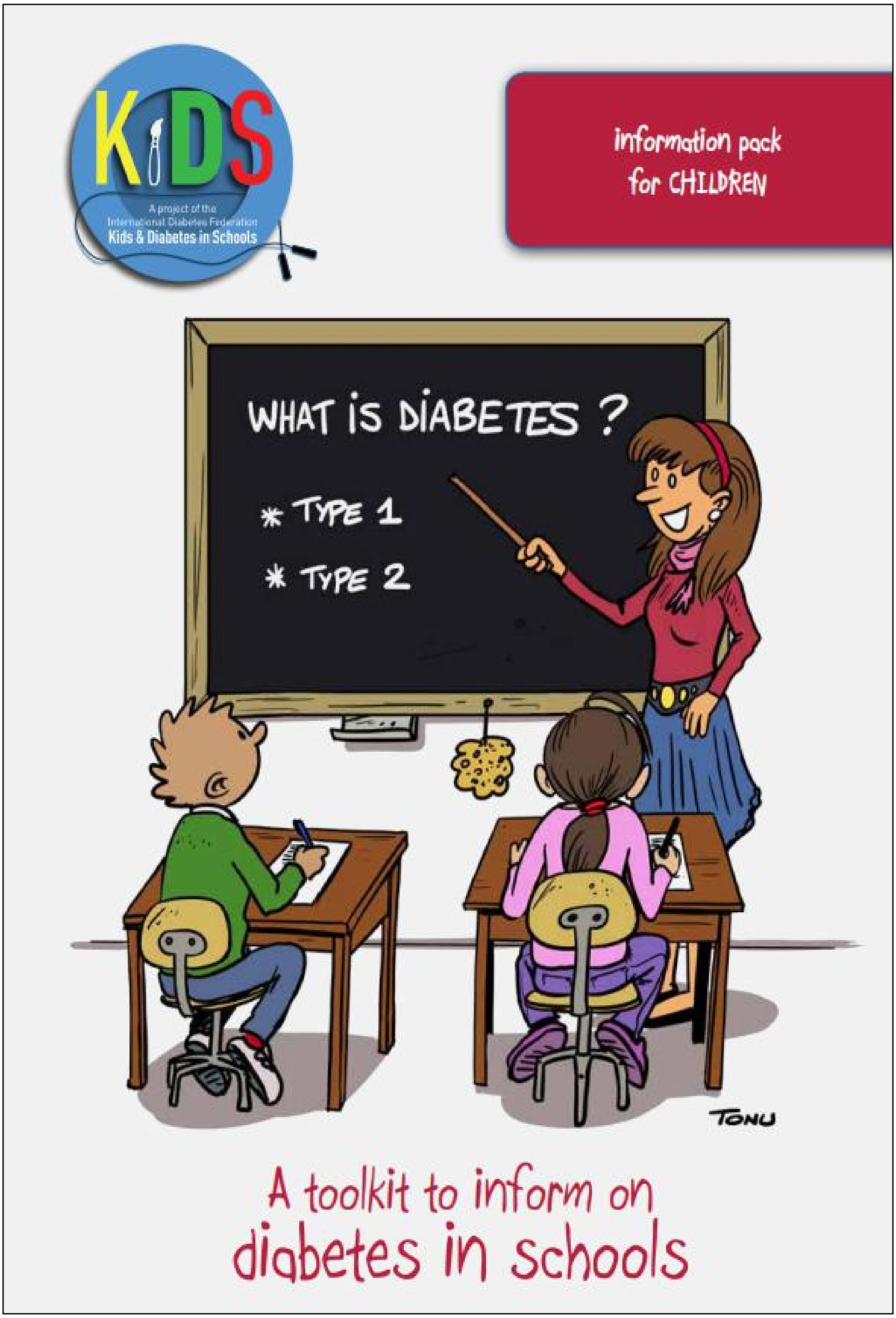
Yours sincerely

Dr Tim Alexander
Deputy Chair, FHS Research Ethics Committee

UNIVERSITY OF HULL

Dr Tim Alexander |Research Co-ordinator| Doctorate Course in Clinical Psychology|Deputy Chair Research Ethics Committee|Faculty of Health Sciences
University of Hull
HU6 7RX, UK
www.hull.ac.uk t.alexander@hull.ac.uk |**01482 464030**

Appendix 7: A toolkit to inform on diabetes in schools (for children)



Acknowledgements:

This material has been developed in collaboration with the members of the KiDS Advisory Committee:

Monika Arora, Anne Belton, David Cavan, David Chaney, Daniela Chinnici, Stephen A. Greene, Agnès Magnen, Angie Middlehurst, Denise Reis Franco, Nikhil Tandon, Sara Webber.

Publication coordinators: David Chaney, Daniela Chinnici (kids@idf.org)

Illustrations: Frédéric Thonar (alias Tonu) www.tonu.be

Layout: Olivier Jacqmain (Publications Manager of IDF)

Partners :

Endorsed by:

The Canadian Diabetes Association supports the International Diabetes Federation's KiDS pack to ensure the health and safety of children with diabetes and to help them be full and equal school participants without fear of exclusion, stigmatization or discrimination.

IDF gratefully acknowledges the support of Sanofi in this project.

Guidelines:

This pack should be used in tandem with an information session and is not intended to be distributed as a standalone item. A programme on diabetes education should be organised at schools around the pack.

If you wish to translate the pack into further languages or make culturally specific adaptations, please notify IDF before any changes are made: communications@idf.org.

IDF, ISPAD and Sanofi Diabetes logos must remain visible on this material. If you have a new local partner that endorses the project, make sure to seek IDF permission before adding new logos on the pack.

We would appreciate your feedback on pack usage and photos from your information sessions.

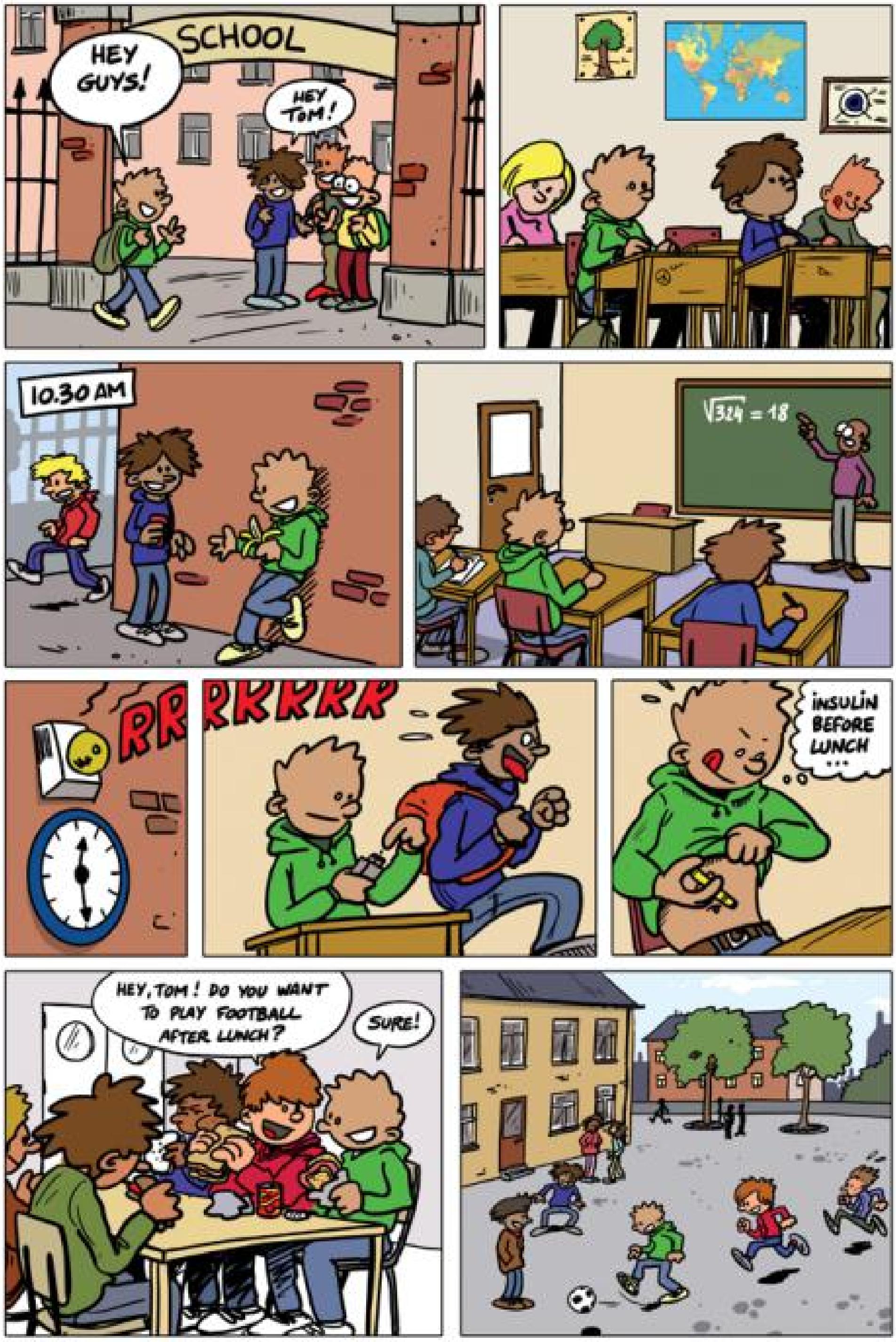
No fees will be asked for using this pack.

CHILDREN

WHAT IS DIABETES?

A day in the life of Tom, living with type 1 diabetes

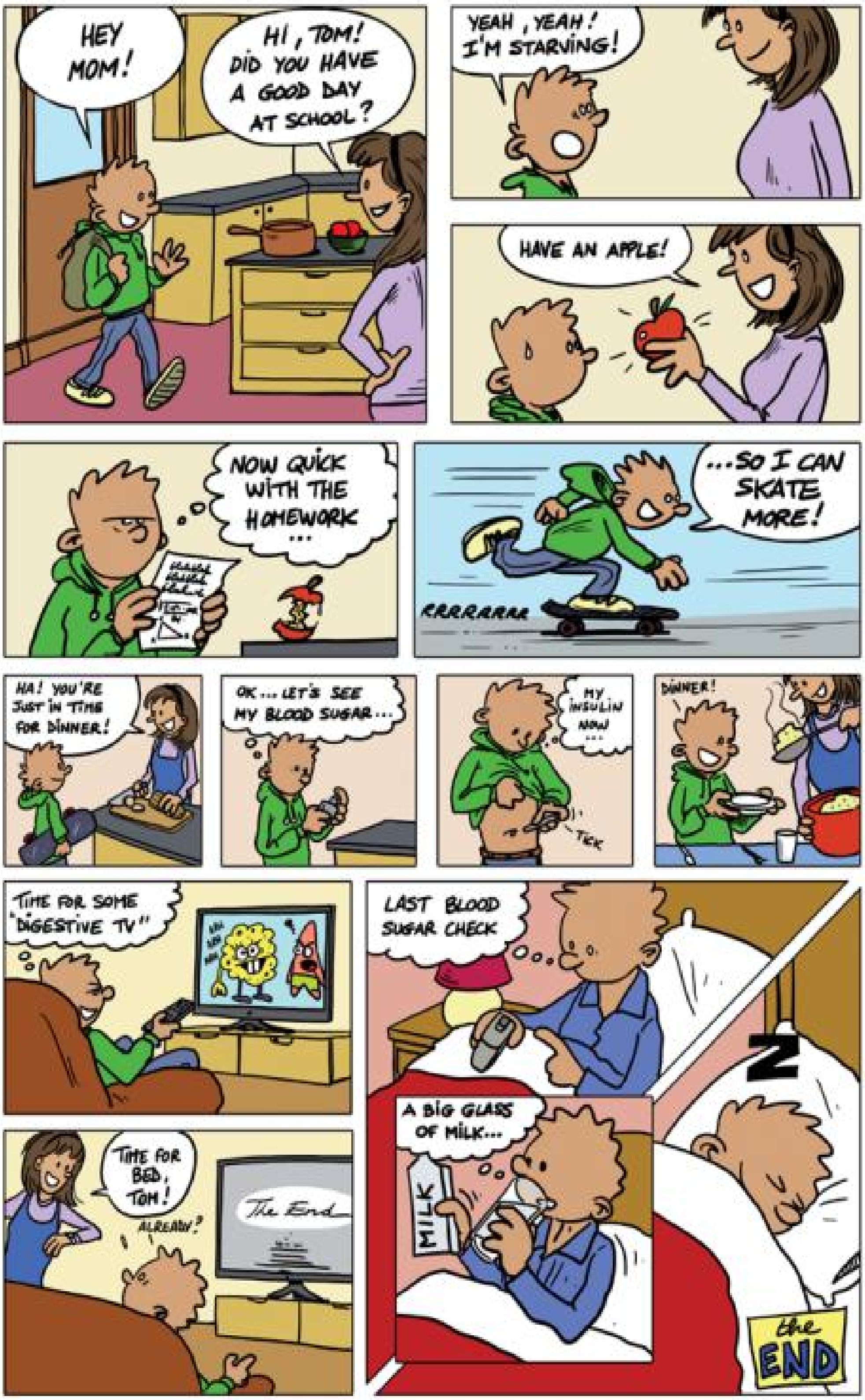
CHILDREN


SCHOOL
HEY GUYS!
HEY TOM!
10.30 AM
$\sqrt{324} = 18$
RRRKKRR
INSULIN BEFORE LUNCH...
HEY, TOM! DO YOU WANT TO PLAY FOOTBALL AFTER LUNCH?
SURE!

CHILDREN


OK GUYS. IT'S TIME FOR YOUR SPORTS CLASS
SPORTS HALL
I'M COMING! I JUST NEED TO CHECK MY BLOOD SUGAR!
I KNOW!
SLURP
SLLUURP
IT WAS GREAT! SEE YOU TOMORROW!
YEAH

CHILDREN


HEY MOM!
HI, TOM! DID YOU HAVE A GOOD DAY AT SCHOOL?
YEAH, YEAH! I'M STARVING!
HAVE AN APPLE!
NOW QUICK WITH THE HOMEWORK ...
...SO I CAN SKATE MORE!
RRRRARRR
HA! YOU'RE JUST IN TIME FOR DINNER!
OK... LET'S SEE MY BLOOD SUGAR...
MY INSULIN NOW ...
TICK
DINNER!
TIME FOR SOME "DIGESTIVE TV"
LAST BLOOD SUGAR CHECK
Z
TIME FOR BED, TOM!
ALREADY?
The End
A BIG GLASS OF MILK...
MILK
the END

CHILDREN

WHY IS IT IMPORTANT TO CHOOSE A HEALTHY LIFESTYLE?

OVERWEIGHT

TIREDNESS

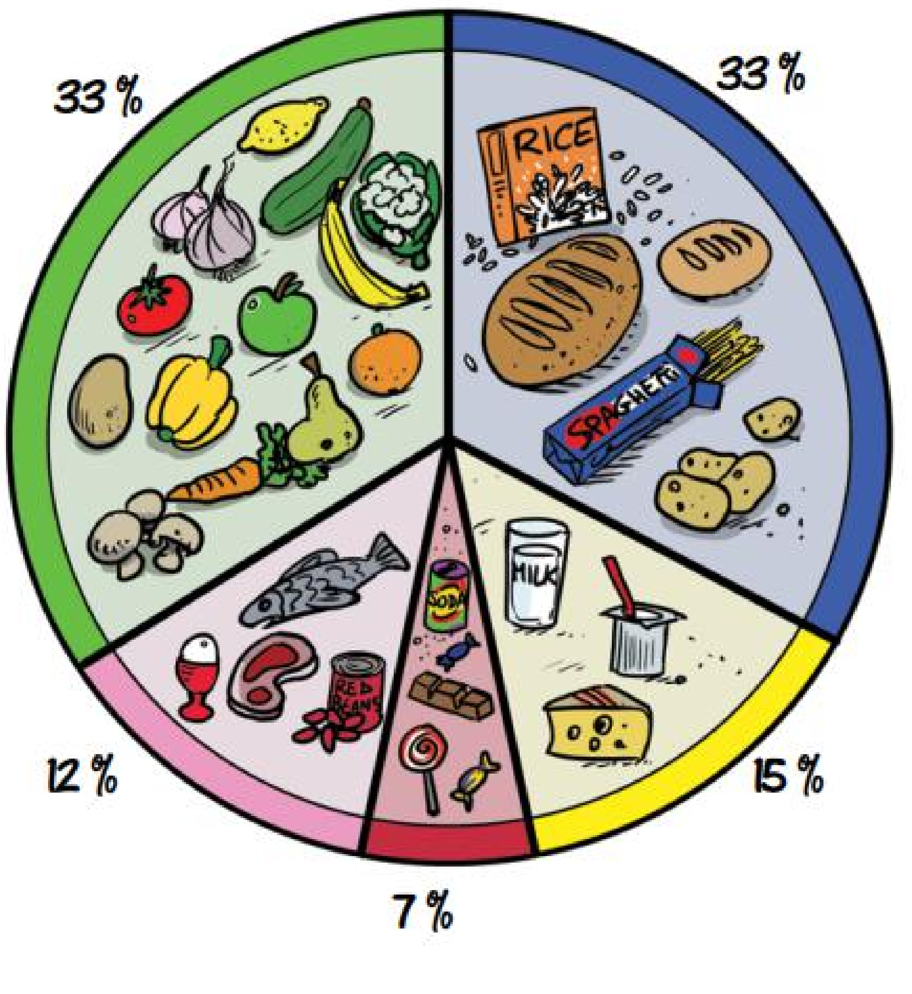
FEELING SICK

UNHEALTHY HEART

HOW TO STAY HEALTHY?
EAT WELL

How to choose healthy food?

THE EATWELL PLATE



Try to remember these proportions in your daily meals.

CHILDREN

HOW TO STAY HEALTHY?
MOVE WELL

A healthy diet is built on a base of regular physical activity, which keeps calories in balance and weight in check.

TIPS TO GET ACTIVE:

- ❑ Try sports and choose a sport you like
- ❑ Set regular times for activities; make it a part of your daily schedule
- ❑ Reduce use of screen time (TV, computers etc..) and play with friends
- ❑ Walk to school
- ❑ Take the stairs instead of an elevator
- ❑ Learn to use the skateboard, the bike or run instead of getting a ride
- ❑ Walk the dog with your parents

CHILDREN

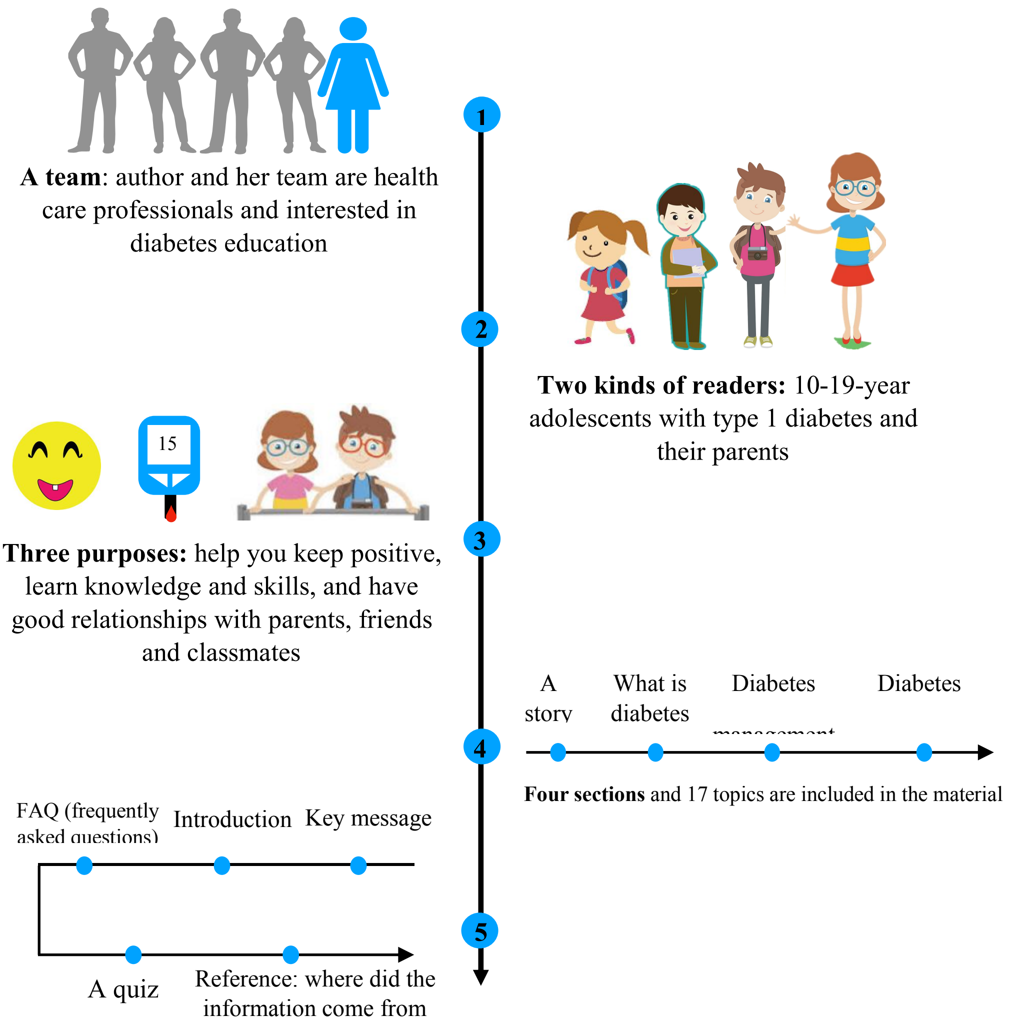
- ❑ Turn off your TV, smart phone or computer and spend some time playing with your friends
- ❑ Stay active: do a minimum of **30 minutes of exercise per day**
- ❑ Exercise with a friend

Appendix 8: The Type 1 diabetes educational material developed in this study

Hi everyone, welcome to open this material.

If you are a 10-19-year-old adolescent with type 1 diabetes, you may find it's not easy to understand and manage your diabetes very well. However, this material is much easier and interesting. It not only tells you about diabetes knowledge and practical skills, but also cares about your mind and thoughts in interesting ways, including figures, tables, questions-and-answers and stories telling.

Following parts will help you know more details about the material.



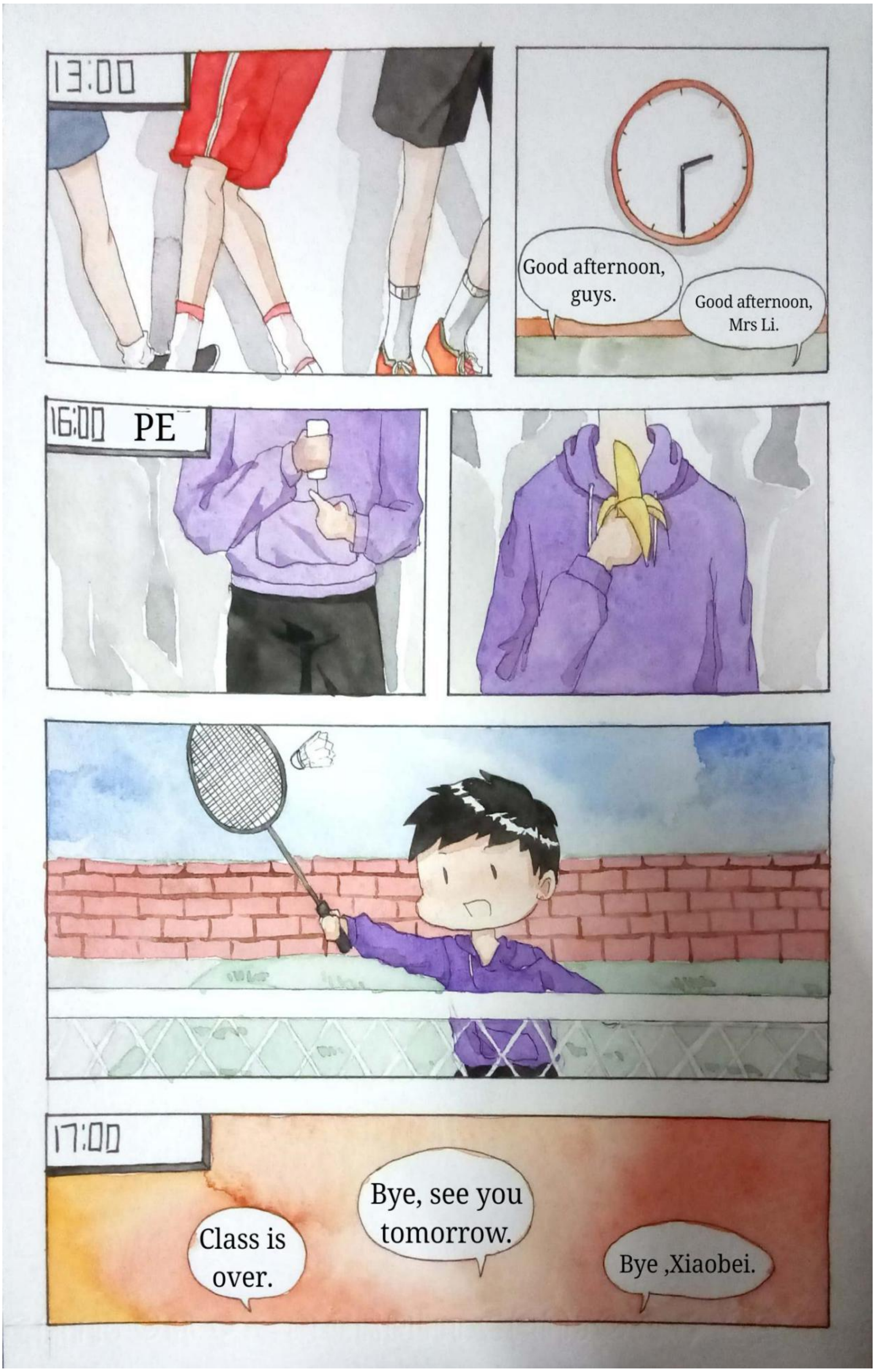
Hope this material would be helpful for you.

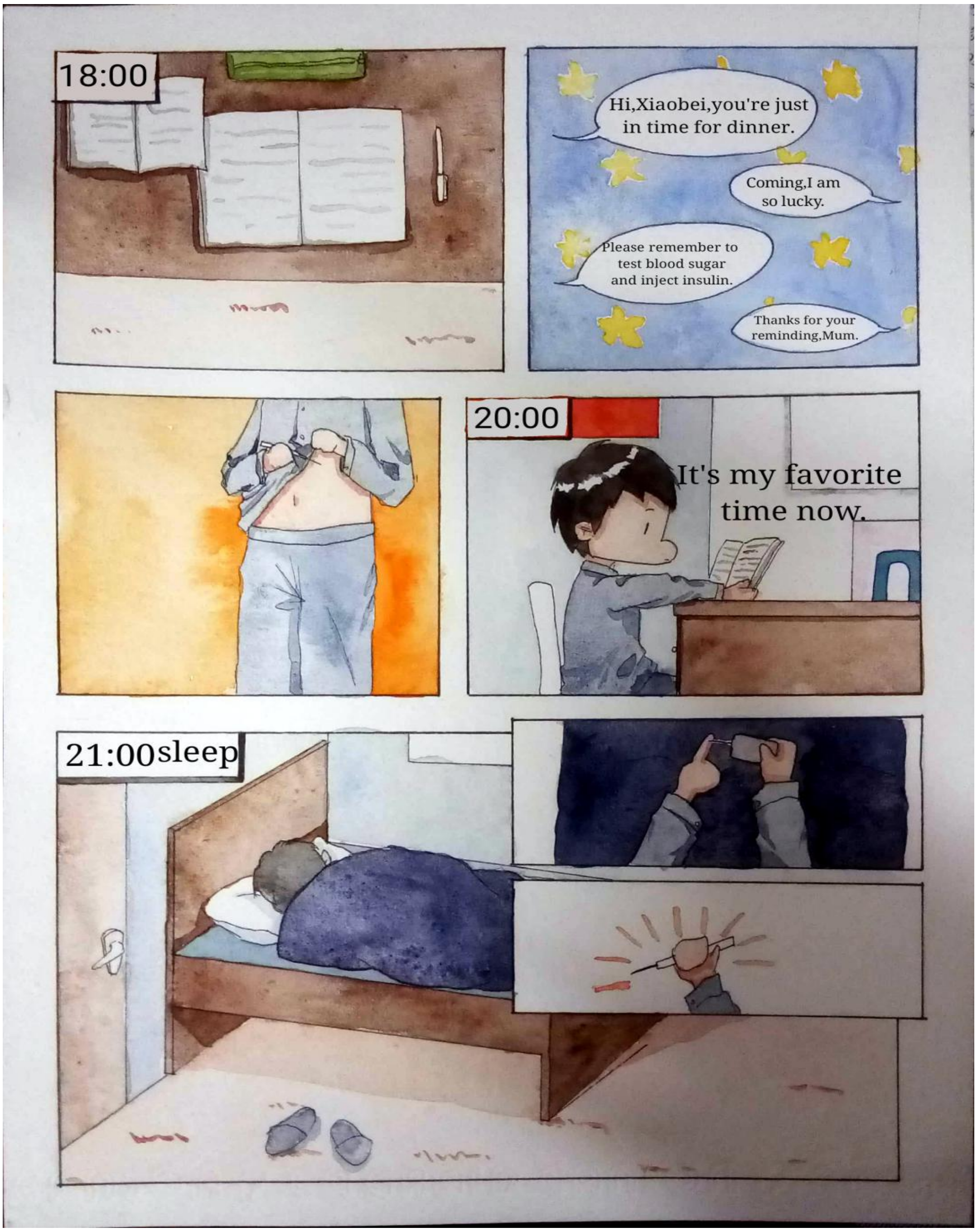
Table of Content

SECTION 1

1.1 A day in the life of Xiaobei, living with type 1 diabetes


7:40
Good morning,Xiaobei.
Good morning.
8:00
泊船瓜洲
京口瓜洲一水
春风又绿江南
Do you have any plan after lunch?
Not yet.
Lunch time now, Xiaobei. Let's go.
Coming soon.
How about playing football with us?
Definitely good.


13:00
Good afternoon, guys.
Good afternoon, Mrs Li.
16:00 PE
17:00
Class is over.
Bye, see you tomorrow.
Bye ,Xiaobei.



References:

International Diabetes Federation (IDF) (2018) KIDS diabetes information pack-a toolkit to inform on diabetes in school. Available online: https://www.idf.org/our-activities/advocacy-awareness/resources-and-tools/73:kids-diabetes-information-pack.html [Accessed 23/10/2018]

SECTION 2

2.1 How did you feel when you were diagnosed with type 1 diabetes

☆ **Key messages:**

- The cause of Type 1 diabetes has no relationship with the candy you eat.
- Type 1 diabetes cannot be cured, but can be controlled well.
- Keeping a positive mind about type 1 diabetes is important. You can have a normal life like your friends or classmates.
- Type 1 diabetes cannot decide your future, but you can.

1. Introduction:

How did you feel when your doctor told you “you are diabetic”? Maybe you didn’t even know what diabetes was, or maybe you worried so much because you thought you were seriously sick. Beibei and Kexin have been diagnosed with type 1 diabetes for years. They can still remember the situation when they were told that they had type 1 diabetes.

I am Beibei, 10 years old. I’ve been diagnosed with type 1 diabetes for 1 year.

Hi Beibei, I am Kexin, 17 years old. I have been diagnosed for 5 year. Beibei, can you still remember the situation when your doctor told you that you had type 1 diabetes.

Yes, Kexin. I remember, at that moment, I even had no idea what diabetes was. And I thought maybe it was like a cold.

They are totally different.

Yes, they are. When I was told that my blood sugar was too high because my body nearly cannot produce a chemical named insulin. I thought maybe it was not a big deal.

I felt so sad and thought maybe I was seriously sick when I was told me that diabetes cannot be cured by my doctor.

But diabetes can be controlled well. Now, my blood sugar is stable. I can finish my study tasks on time and play my favourite skateboard.

That’s right. If you follow doctor’s treatment regimen and keep stable blood sugar, you can also have a normal life, like your classmates.

Last winter holiday, I went to Hainan with my parents. We had a good time there.

Having a positive mind is also important.

Beibei, you are right. At the beginning, I thought maybe I had diabetes because I did something wrong.

Me too. I thought I had type 1 diabetes because I like candy.

Actually, the cause of type 1 diabetes has no relationship with the candy we ate.

Yes. We also didn't do something wrong. For our friends or others, their body can produce insulin, but ours nearly cannot. That's the difference.

There was a period of time when I didn't want to play with my friends because I thought I was different from them.

In fact, we are different from them because we need to pay more attention to our body and blood sugar. On the other hand, we have no big difference with our friends because diabetes can't control your life and stop you from doing things. You just need to plan a little more.

You are right. Diabetes cannot decide our future, but we can.

2. References:

Miller, S. (1999) Hearing from children who have diabetes. Journal of Child health Care, 3(1): 5-12

healthtalk.org (2017) Managing diabetes as a teenager. Available online: http://www.healthtalk.org/young-peoples-experiences/diabetes-type-1/managing-diabetes-teenager [Accessed 13/10/2018]

2.2 What is diabetes—the relationship among blood sugar, insulin and diabetes

☆ **Key messages:**

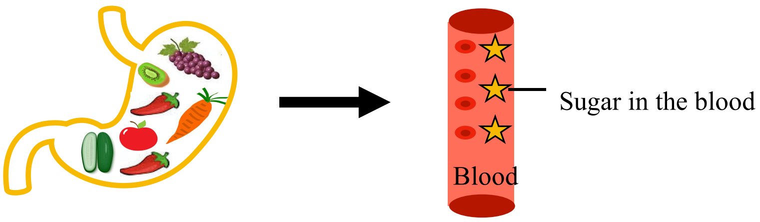
- Blood sugar refers to the sugar in our blood, and mainly comes from our food.
- Insulin is produced by our pancreas, and works as a key to open doors of our cells, which can let sugar go into the cells to provide energy for us.
- For people with type 1 diabetes, your body nearly cannot produce insulin, which causes sugar to build up in your blood.

1. Introduction:

The question "what is diabetes?" is often asked during diagnosis and it is still useful to review even if you have diagnosed for a period of time. The relationship between blood sugar and insulin is helpful for us if we want to figure out what diabetes is.

(1) What is blood sugar?

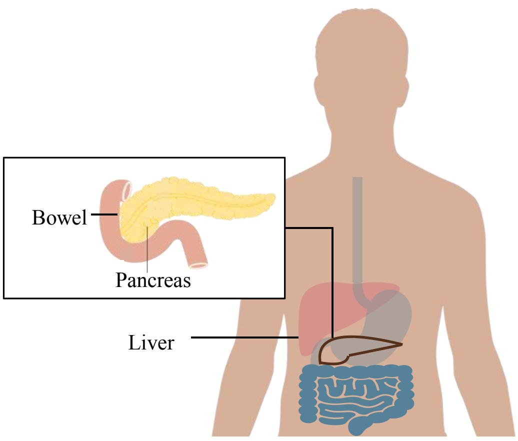
- Blood sugar literally refers to sugar in the blood.
- Blood sugar mainly comes from our food.



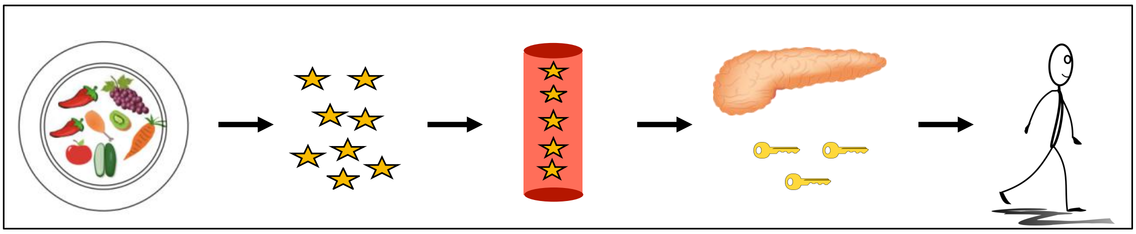
- Sugar can provide energy for us, which needs the help of insulin.

(2) What is insulin?

- Insulin is produced by pancreas. Pancreas is an organ in our body and lies behind our stomach.



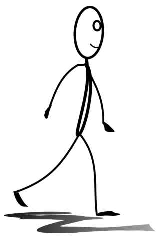
- Insulin can help sugar move from blood to cells to provide energy for us.



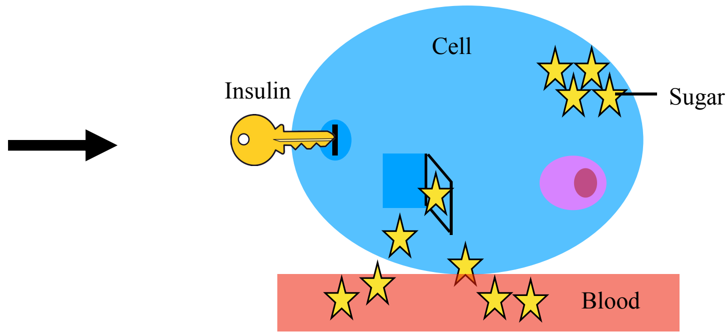
Food we eat. | Foods change into sugar. | Sugar goes into blood. | Pancreas produces insulin | Insulin helps sugar go into our cells to provide energy for our body.

(3) The relationship among blood sugar, insulin and diabetes

- For your friends without diabetes, their body can produce insulin, which works as a key to open the doors of our cells to let sugar go into cells from blood.

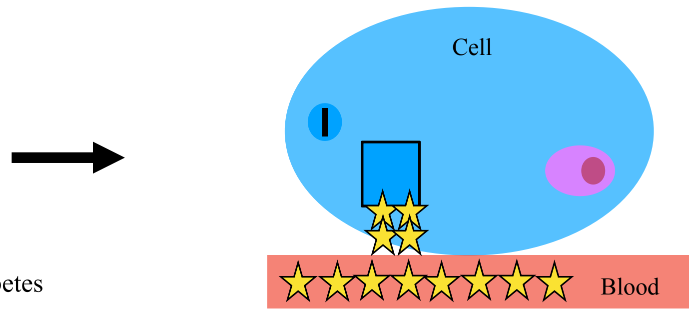


People without diabetes



- For people with type 1 diabetes, like Beibei, Kexin or you, your body nearly cannot produce insulin. It means sugar cannot go into cells and only stay in the blood.

Beibei with type 1 diabetes



2. Frequently asked questions

- Is insulin addictive?

Kele, 17 years old, type 1 diabetes
@ Miss Chen Hi Miss Chen, I am Kele, 17 years old. I was diagnosed with type 1 diabetes last month.

Miss Chen, Registered Nurse

@ Kele Hi Kele, I'm very happy to receive your message. How can I help you?

Kele, 17 years old, type 1 diabetes

@ Miss Chen Since I was diagnosed, I've been told by many people that insulin injection is addictive. Is that true?

Miss Chen, Registered Nurse

@ Kele Kele, it's not true. Insulin is not addictive.

- Insulin is a kind of chemical, which can be produced by our body.
- Insulin is very important for everybody because it is the only stuff to lower our blood sugar.
- However, for type 1 diabetes, you need to inject insulin all the time because your body nearly can't produce insulin.

3. A quiz (you can try to write down you answers on the paper):

Please read each statement, then indicate it is true or false：

1) Insulin is the only stuff to lower our blood sugar. True/False/Don't know

2) Insulin is produced by our kidney. True/False/Don't know

3) Without insulin, sugar in the blood can also go into our cells to provide energy for us. True/False/Don't know

Note: Please find the answer at the end of this article.

4. References:

Craig, M. E., Jefferies, C., Dabelea, D., et al (2014) Definition, Epidemiology, and Classification of Diabetes in Children and Adolescents. Pediatric Diabetes, 15 (Suppl. 20): 4-17

Wolfsdorf, J. I., Allgrove, J., Craig, M. E., et al (2014) A Consensus Statement from the International Society for Pediatric and Adolescent Diabetes: Diabetic ketoacidosis and hyperglycemic hyperosmolar state. Pediatric Diabetes, 15 (Suppl. 20): 154-179

Ly, T. T., Maahs, D. M., Rewers, A., et al (2014) ISPAD Clinical Practice Consensus Guidelines-Hypoglycemia: Assessment and management of hypoglycemia in children and adolescents with diabetes. Pediatric Diabetes, 15 (Suppl. 20): 180–192

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (2016) What is diabetes? Available online: https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes [Accessed 18/10/2018]

Answers to the quiz
The answers are “True, False, False”. If you answered them correctly, congratulations! If not, do not worry, you can read the content repeatedly.

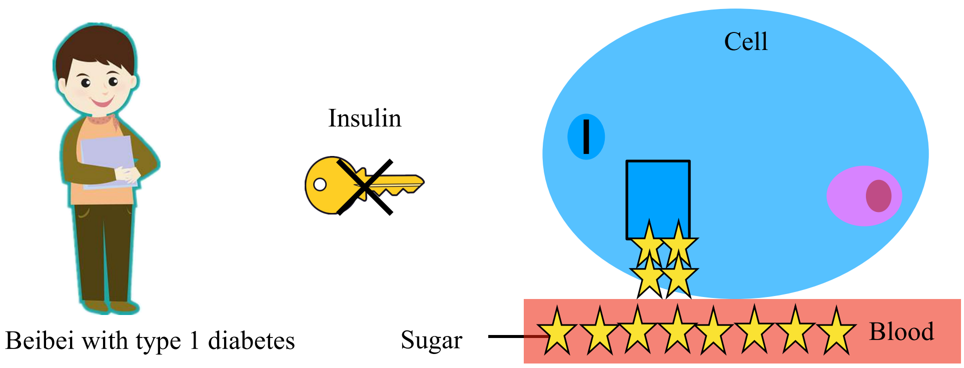
☆ **Key messages:**

- Type 1 diabetes occurs when your body nearly can’t make insulin any more.
- Immune system destroys pancreas cells that make insulin so that insulin nearly can’t be produced.
- For type 1 diabetes, you may experience some symptoms, such as always feel hungry, always feel thirst and going to toilet, eating much but still weight loss.

1. Introduction:

(1) What is type 1 diabetes?

- Type 1 diabetes occurs when your body nearly can’t make insulin any more, which will cause sugar to build up in your blood. It was shown that some people with type 1 diabetes can still produce limited insulin.
- For example, our pancreas can be seen as a factory and insulin can be regarded as key. When there is no key produced, the doors of our cells cannot be opened. Sugar can only stay in the blood, rather than go into cells.



(2) Causes of type 1 diabetes

- At this moment, maybe you do have a question “why can’t my body produce insulin nearly?”
- Good question! Actually it’s mainly about your immune system.
- The immune system always protects our body. However, it sometimes can decide to attack itself.
- For those with Type 1 diabetes, your immune system recognises pancreas as “nasty”, therefore, attacks it. That’s why insulin nearly cannot be produced in your body.

- Type 1 diabetes is also related to genetic and environmental factors.

(3) Symptoms of type 1 diabetes

- Symptoms of type 1 diabetes usually happen quickly, over a few days to weeks.
- For people with type 1 diabetes, they may have one or several symptoms mentioned below. Could you remember if you experienced some symptoms below?

Always hungry, especially after eating

Always thirst

Always go to toilet

Unexplained weight loss

Always tired

Wounds that won’t

Blurred version

(4) Diagnosis of type 1 diabetes

- You may be curious about how you were diagnosed by your doctor.
- Actually, you could be asked if there are any symptoms. Blood sugar levels also play an important role in the diagnosis of diabetes. If your fasting blood sugar (without eating food for 10 hours and drinking for 8 hours) is more than 7.0 mmol/L, or blood sugar at any times is more than 11.1mmol/L, you could be diagnosed with diabetes.
- If anyone needs to be diagnosed with type 1 diabetes, the doctor would check some blood indicators and the age.

2. Frequently asked questions:

- I was told that I had type 1 diabetes because I ate too much sugar. Is this true or not?

Sisi, 10 years old, type 1 diabetes

@ Miss Chen Miss Chen, I am Sisi and I was diagnosed last week. These days, my mum always said I had type 1 diabetes because I ate too much sugar. Is this true?

Miss Chen, Registered Nurse

@ Sisi It's a good question, Sisi. But it is totally wrong.

- As mentioned above, people like you have type 1 diabetes because of immune problem. Their pancreas nearly cannot produce insulin. That's the problem.

Sisi, 10 years old, type 1 diabetes

@ Miss Chen Does that mean I can eat candy without limit?

Miss Chen, Registered Nurse

@ Sisi It's not right.

- Your body cannot produce insulin to use extra sugar you eat, which will raise your blood sugar. Too much sugar in your blood could be dangerous for you.
- Please continue reading our material. How to eat food in a health way will be mentioned in the third chapter "how to manage diabetes".

3.**A quiz** (you can try to write down you answers on the paper):

1) Which of the following factors are related to type 1 diabetes:

A. Immune system B. Environmental factor C. genetic factor D. All of the above

2) Which of the following Symptoms won't happen to most people with type 1 diabetes:

A. Always feel thirsty B. Always feel hungry and eat too much C. increasing weight D. Wounds won't heal

3) About diagnosis of type 1 diabetes, which of the following factors need to be considered:

A. Age B. Blood sugar values C. Some blood indicators D. All of the above

Note: Please find the answer at the end of this article.

4. References:

Craig, M. E., Jefferies, C., Dabelea, D., Balde, N., Seth, A., Donaghue, K. C. (2014) Definition, epidemiology, and classification of diabetes in children and adolescents. Pediatric Diabetes, 15 (Suppl. 20): 4–17

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (2017) Type 1 diabetes? Available online: https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/type-1-diabetes [Accessed 18/10/2018]

Answers to the quiz
The answers are “D, C, D”. If you answered them correctly, congratulations! If not, do not worry, you can read the content repeatedly.

2.4 How does type 1 diabetes make you feel

☆ **Key messages:**

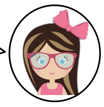
- Keep a positive mind and believe your blood sugar levels can be controlled well.
- Even though diabetes management is not easy, try to be friend with it.
- For young adolescent, letting parents be your supervisor of diabetes management is a good idea.

1. Introduction:

How long have you been diagnosed with type 1 diabetes? Maybe several weeks, months or years. How does diabetes make you feel? Following is the discussion among Xiaoxue, Kexin with type 1 diabetes and Doctor Ma, a psychologist who can provide mental health care.

Hi everyone, I'm Doctor Ma, a psychologist. Today we will talk about feelings about type 1 diabetes. Kexin and Xiaoxue will be with us.

Hi Doctor Ma and Xiaoxue, I am Kexin, 17 years old. I've been diagnosed with type 1 diabetes for 5 years. Nice to talk with you.



Hi everyone, I am Xiaoxue and 15 years old. I've been diagnosed for 1 years.

The first topic is "how do you treat type 1 diabetes?"

I take my diabetes seriously. Diabetes is a long-term disease, which could have serious effects if you can't control your blood sugar well.

I agree with Kexin. Even though diabetes cannot be cured, but it can be controlled well. We need to keep a positive mind.

But somebody told me that "you don't need to care about diabetes because only a minority of people could have a bad ending".

I think diabetes is not a kind of fortunate thing. It's not a lottery thing.

I think so. If we do nothing to control our blood sugar, we could have a bigger chance to experience these bad ending.

Kexin and Xiaoxue, you are right. On one hand, we need to keep a positive mind and believe that diabetes can be controlled well. On the other hand, we need to take it seriously to prevent a bad ending.

The second topic is “how does type 1 diabetes make you feel?”

I found diabetes is hard for me. I view diabetes as one part of my lives, try to handle it and get along with it. However, to some degree, the blood sugar levels are not very good all the time.

You cannot stop caring about your diabetes. There was a period of time when I was busy preparing for an exam. You can image that my blood sugar became more than 15.0 mmol/L.

Yes, summer holiday was my favourite holiday. I can have a good holiday with my parents. But now I need to prepare well and pay more attention to my body when I leave home.

Sometimes, that does make me feel frustrated.

Girls, do not be sad. It is not easy to take care of your diabetes, especially when you are adolescents. Treat diabetes as your friend, try to know it and find your way to get along with it. Talking with somebody else with type 1 diabetes is helpful.

But remember that everyone has different treatment regimen. Do not change your treatment by yourself.

The third topic is “do you have any other complaint?”

Yes, I do have one. Why do my doctors and parents go on about “good blood sugar”?

I know blood sugar levels are very important for me. But once my blood sugar is not good, my parent could asked if I eat too much or miss my insulin. That makes me feel not good.

Actually, I also met the same situation. I feel frustrated. Once I had a talk with my parents, I began to understand my parents. My mum told me that she worried me and my diabetes so much.

My mum worried that I could experience some serious complications in the future if my blood sugar was not good. She hopes I can have a normal life like my friends.

Therefore, that's why they become more sensitive. But I always feel inpatient with their excessive concerns, which makes me have a difficult relationship with my parents.

After that talk, I invited them to supervise my diabetes management. I write down my blood sugar values every time, which is helpful to know the trend of my blood sugar. From that time on, my parents began to believe that I can manage my diabetes very well.

That's a good idea.

Well done, Kexin. You not only manage your diabetes well, but also win the trust from parents by positive communication and your action.

2. References:

Campbell, R., Pound, P., Pope, C., Britten, N., Pill, R., Morgan, M., Donovan, J. (2003) Evaluating meta-ethnography: a synthesis of qualitative research on lay experiences of diabetes and diabetes care. Social Science & Medicine, 56: 671-684

Davidson, M., Penney, E. D., Muller, B., Grey, M. (2004) Stressors and self-care challenges faced by adolescents living with type 1 diabetes. Applied Nursing Research, 17(2): 72-80

SECTION 3

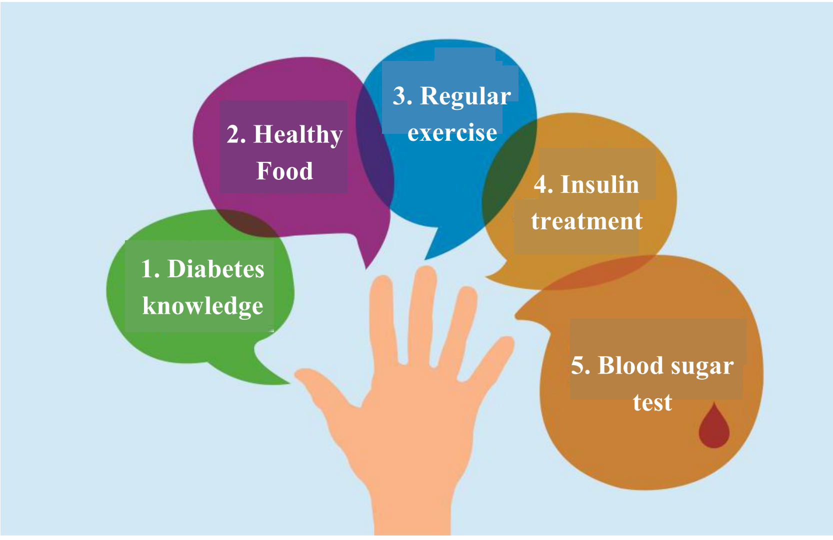
3.1 How to manage type 1 diabetes-knowledge and food

☆ **Key messages:**

- There are five components you need to do to manage type 1 diabetes.
- Search diabetes information from reliable resources. Do not be misled by false advertising.
- Healthy food with low in fat and added sugar is necessary for everyone with type 1 diabetes.

1. Introduction:

- It may make you feel frustrated when you are told that type 1 diabetes cannot be cured. At this moment, type 1 diabetes still cannot be cured. However, it can be controlled. What can you do?
- Five components of type 1 diabetes management



(1) Diabetes knowledge

- Take myself for example. My dream is to be a nurse. In order to be qualified to take care of patients, I need to learn nursing knowledge all the time. So does diabetes management. If you want to manage your diabetes well, learning diabetes knowledge is basic and key.
- Please find diabetes information from reliable resources, such as materials or official accounts from hospitals, or your community.

- Do not be misled by advertising in reality or on the internet. Following is the talking between Kexin and Xiaoxue about false advertising.

Five years ago, I was just diagnosed with type 1 diabetes. There were a period of time when my families can't accept the facts. My parents still believed that there must be some methods to cure me.

Yes, it took a period of hard time to accept the facts, including parents.

At that moment, once somebody told my parents that there were some methods to cure me, my parents could let me try. I tried so many "wonder cures".

Did they work?

Xiaoxue, obviously not. My blood sugar levels were still high, and even I was sent to hospital because of high blood sugar.

Kexin, I also had similar experiences. My grandparents often liked watching TV shopping. Once a day, they took many medicine to my parents and said these can cure me. It was a so-called expert who sold these medicines to my grandparents from a hotline and said he had cured many people.

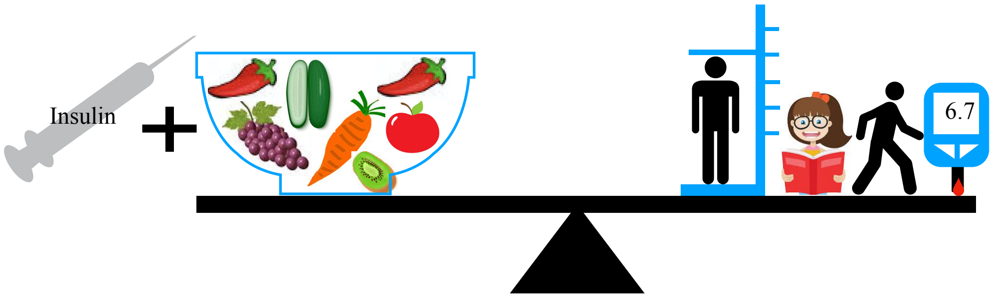
These medicines must be expensive and can't work. Your blood sugar could become much higher, even you can have coma because of constant high blood sugar, which are so dangerous for us.

You are right, Kexin. Hope our experiences can help others far from these false advertisements.

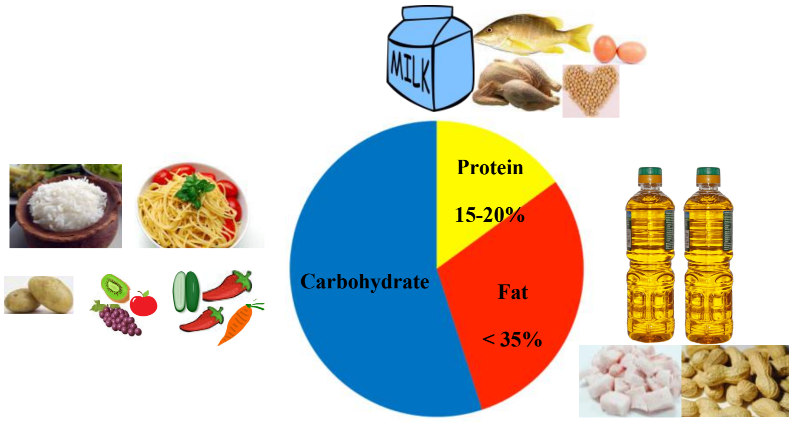
- If you have any questions about diabetes information from others, please do not be shy to ask your doctors or diabetes nurses.

(2) Healthy food

- Healthy food refers to the food with low in fat, sodium and added sugar, high in fibre, and with rich vitamin and minerals like Calcium.
- Healthy food is necessary for everyone, including those with type 1 diabetes.
- For adolescents with type 1 diabetes, you may want to know how much you can eat. Actually, with appropriate insulin, the food you eat should maintain your optimal growth, daily life and exercise, and keep optimal blood sugar.



- Three kinds of nutrition which need to be involved in your food:



2. A quiz (you can try to write down you answers on the paper):

1) The diabetes food is:

A. Healthy food for most people B. Some food specifically for people with diabetes

2) Which of following is highest in carbohydrate:

A. Chicken B. Potato C. Honey

3) Which of following is highest in fat:

A. Low fat milk B. Fruit juice C. Honey

4) Any food that has "sugar free" label is the "free food":

A.Yes B. No

Note: Please find the answer at the end of this article.

3. Frequently asked questions:

1) Carbohydrates (carbs) are the main resources of sugar. Can I control my blood sugar by reducing carbs.

Kele, 17 years old, type 1 diabetes

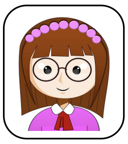
@ Miss Wang Hi Miss Wang, can I reduce carbs food to control my blood sugar?

Miss Wang, Dietician

@ Kele Hi Kele, the answer is no.

- It is an international agreement that carbohydrates should not be restricted among adolescents with type 1 diabetes, which could affect their growth.

2) People with type 1 diabetes cannot eat fruit.



Sisi, 10 years old, type 1 diabetes

@ Miss Wang Hi Miss Wang, I was told fruit is full of sugar and people with type 1 diabetes cannot fruit.

Miss Wang, Dietician

@ Sisi It's totally wrong. People with diabetes can have fruit.

- Fruits are loaded with vitamins, minerals and fibre just like vegetables.
- The best choices are fresh fruit, fruit juice or dried fruit without added sugars.
- However, the carbohydrate fruits contain can quickly be transformed into sugar. If you eat fruit, you need to reduce some of other food with carbs, such as rice, noodles or potato.

3)These specially labelled diabetes foods must be unlimited for people with type 1 diabetes.

Kele, 17 years old, type 1 diabetes

@ Miss Wang Miss Wang, these specially labelled diabetes foods must be unlimited for me.

Miss Wang, Dietician

@ Kele Kele, such foods are not recommended.

- These "diabetic" food are not necessary and expensive.
- It was reported many of these products carrying the label are not any lower in fat and calories, which is not beneficial for diabetes management.

5. References:

Smart, C. E., Annan, F., Bruno, L. P. C., Higgins, L. A., Acerini, C. L. (2014) Nutritional management in children and adolescents with diabetes. Pediatric Diabetes,15 (Suppl. 20): 135-153

American Diabetes Association (2016) Fruits. Available online: http://www.diabetes.org/food-and-fitness/food/what-can-i-eat/making-healthy-food-choices/fruits.html [Assessed 8/11/2018]

Diabetes UK (2016) 'Suitable for diabetics' labels off the shelves from today. Available online: https://www.diabetes.org.uk/about_us/news/suitable-for-diabetics-food-labels-outlawed-from-today [Assessed 8/11/2018]

Answers to the quiz

The answers are "A, B, A, B". If you answered them correctly, congratulations! If not, do not worry, you can read the content repeatedly.

3.2 How to manage type 1 diabetes-exercise and insulin treatment

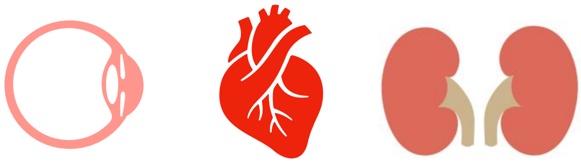
☆ **Key messages:**

- Regular exercise is helpful for your diabetes management.
- Insulin treatment regimens could be individualised.
- Store insulin in correct methods.

1. Introduction:

(3) Regular exercise

- You may doubt if exercise has any benefit for your diabetes management.
- The answer is yes. Exercise can help your body to use insulin more effectively. Regular exercise can reduce the amount of insulin you need to inject, lower you blood sugar, and reduce the risk of long-term complications.
- In some cases, exercise should be cautious.

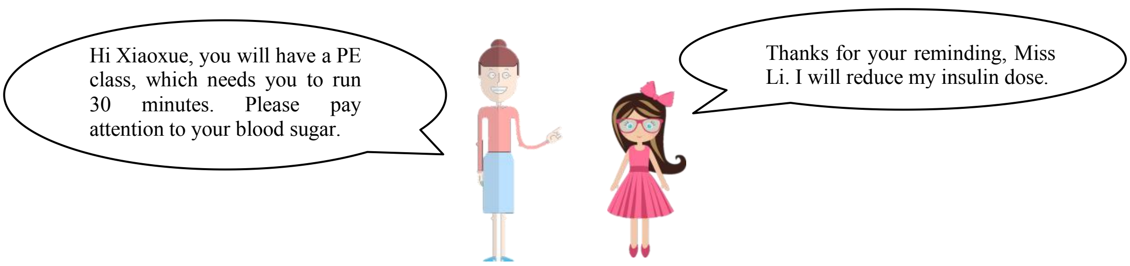


Eye damage　　Heart damage

If you experienced these damage caused by diabetes, you need to get permission from doctors to

Any exercise should be avoided if pre-exercise blood sugar is > 14 mmol/L.

- Blood sugar needs to be measured before and after exercise because low blood sugar may happen up to 24 hours after exercise.
- Before exercise, insulin dose needs to be reduced or you can eat a little bit more to avoid low blood sugar. Preparing candy is also necessary during exercise.



(4) Insulin treatment

- When is it the best time for people with type 1 diabetes to use insulin? For type 1 diabetes, you could be suggested to inject insulin as soon as you are diagnosed by your doctor.

- It's normal that you may inject different kinds or amounts of insulin from others. You need to follow your own treatment regimen.

- Of course, your doctor would also adjust your treatment regimen according to your blood sugar controlling. And sometimes, you also need to adjust by yourself according to the food you eat, exercise you do, blood sugar levels and your doctors' suggestions.

- Four types of insulin:

Rapid-acting insulin (such as Novolog): can work 2-4 hours in our body

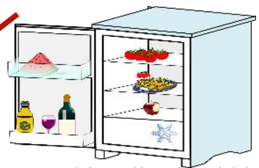
Short-acting insulin (such as Novolin R): can work 3-6 hours in our body

Intermediate-acting insulin (such as Novolin N): can work 12-18 hours in the our body

Long-acting insulin (such as lantus): can work over 24 hours in our bodv

- How to store insulin:

Once opened, insulin can be put in the house



Unused insulin should be in refrigerator (2-8℃).

If you prepare to travel, please put insulin in the cooler bag.

Freezer

Windowsill with sunshine

Heater

- Some insulins have slightly different storage needs, so please read the patient information leaflet that comes with yours.

2. Frequently asked questions:

1) Is high-intensive exercise better than low-intensive exercise?

Kele, 17 years old, type 1 diabetes

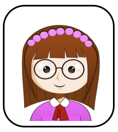
@ Doctor Li Doctor Li, is high-intensive exercise better than low-intensive?

Doctor Li, Doctor in diabetes

@ Kele It’s not true.

- However, it is recommended that teens with diabetes should be encouraged to take part in at least 60 min of moderate exercise at least 3 days a week.
- Choose the exercise items you like and you can do.
- Increase exercise gradually from 10 min to 30 min if you have no exercise habit.
- It is reported that high intensity exercise has a higher risk of low blood sugar even though it is more effective in improving heart fitness among people with diabetes. Therefore, it is controversial whether people with type 1 diabetes should be recommended to exercise in high intensity.

2) Can exercise cause low blood sugar? What can I do to prevent low blood sugar?



Sisi, 10 years old, type 1 diabetes

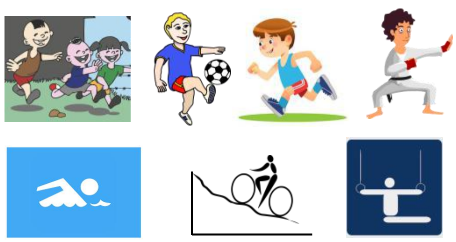
@ Doctor Li Hi Doctor Li, what can I do to prevent low blood sugar?

Doctor Li, Doctor in diabetes

@ Sisi Low blood sugar can happen during or after exercise. However, if you do well, low blood sugar can be avoidable.

- Before and after exercise, frequent blood sugar monitoring is very important. Low blood sugar can happen shortly after exercise or up to 24 hours afterwards.
- Adjust your food and insulin dose before exercise according to blood sugar levels.
- Prepare some snacks during exercise.

Moderate exercise: when you exercise, you can talk but cannot sing the words to a song.



Vigorous exercise: if your activity is vigorous, you won’t able to say more than a few words without pausing for a breath.

3. A quiz (you can try to write down you answers on the paper):

Please read each statement, then indicate it is true or false：

1) Unopened Insulin penfill can be put in the house (<25°). True/False/Don't know

2) Low blood sugar can only happen during exercise, rather than after exercise. True/False/Don't know

3) For adolescents with type 1 diabetes, it is better to have exercise with higher intensity. True/False/Don't know

Note: Please find the answer at the end of this article.

4. References:

Robertson, K., Riddell, M. C., Guinhouya, B. C., et al (2014) Exercise in children and adolescents with diabetes. Pediatric Diabetes, 15 (Suppl. 20): 203-223

Danne, T., Bangstad, H. J., Deeb, L., et al (2014) Insulin treatment in children and adolescents with diabetes. Pediatric Diabetes, 15 (Suppl. 20): 115-134

American Diabetes Association (2015) Insulin basics. Available online: http://www.diabetes.org/living-with-diabetes/treatment-and-care/medication/insulin/insulin-basics.html[Accessed 30/10/2018

Riddell, M. C., Gallen, I. W., Smart, C. E., et al (2017) Exercise management in type 1 diabetes: a consensus statement. Lancet Diabetes Endocrinol, 5(5):377-390

Answers to the quiz

The answers are "False, False, False". If you answered them correctly, congratulations! If not, do not worry, you can read the content repeatedly.

3.3 How to manage type 1 diabetes-insulin injection technology1

☆**Key messages:**

- Follow your doctor's suggestions about when and how many time you need to inject insulin.
- Avoid injecting in the same site repeatedly. Injection rotation is important and effective.
- Insulin pen is more common and convenient to use.

1. Introduction:

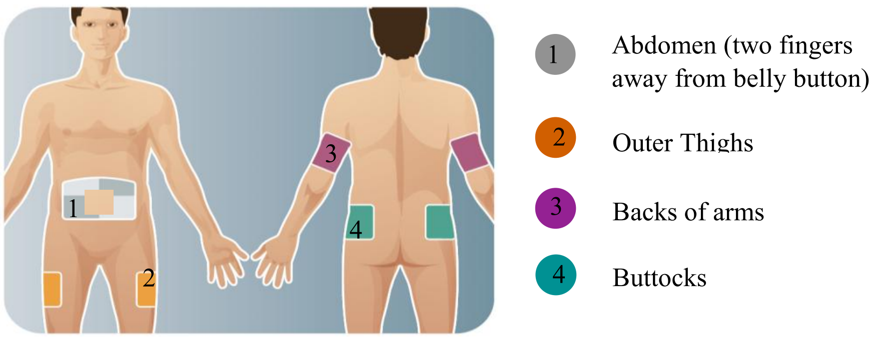
Insulin injection is a necessary technology everyone with type 1 diabetes needs to learn. Maybe you have injected by yourself, or maybe you are preparing to learn how to inject. Let's revisit the main point to inject insulin.

(1) When to inject insulin

• Your doctor could tell you which kind of insulin you need to use, when and how many time you need to inject.

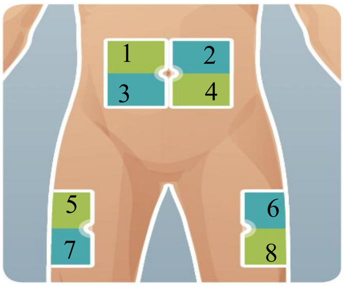
• Please follow your doctors' treatment regime and do not change it by yourself.

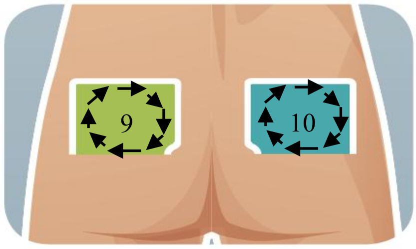
(2) Injection site



• If you choose abdomen to inject, keeping two fingers away from the belly button.

• Avoid injecting in the same site repeatedly. Inject in one of the zones every week and move away. Injection in a certain zone should be spaced at least 1 cm from each other.





(3) Choosing an injection device

• The injection devices mainly include syringes and pens.

• Insulin pens include prefilled pen (penfill can't be replaced) and reusable pen (penfill is replaceable).

(4) How to inject insulin by using insulin pen

1) Preparing a pen for injection

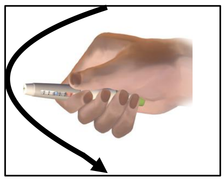
1

Wash hands

2

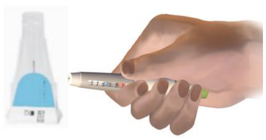
Check insulin type and expiration date

3



Just intermediate and premixed insulin need to roll

4



Put a new pen needle on, and remove the cap

5

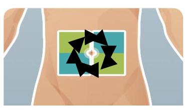
Prime 2 units to make sure a drop of insulin comes out

6

Dial the units you need

2) Delivering an injection by using insulin pen

1



Select an injection site according to your rotation plan, such as the abdomen

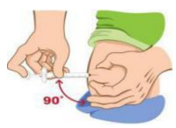
2

Make sure skin is clean

3

Pinch the skin by using your thumb and first finger

4

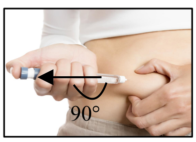


Insert needle quickly and at a 90-degree angle

5

Inject insulin with your thumb steadily

6



10 seconds later, pull out the needle

7

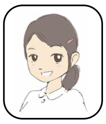
Remove and throw the needle carefully and safely

2. Frequently asked questions:

1) What should I do if insulin leaks out after the injection?

Kele, 17 years old, type 1 diabetes

@ Miss Chen Miss Chen, what should I do if insulin leaks out after the injection?

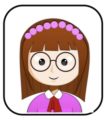


Miss Chen, Registered Nurse

@ Kele Sometimes, a small drop of insulin may leak out from your needle, even if you have left the needle in the skin for 5-10 seconds.

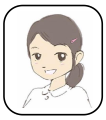
- Generally, the amount of insulin lost in this situation is minimal and will probably not affect your blood sugar control.
- Some tricks may be helpful: pinching your skin before injection, injecting at a 45-degree rather than 90-degree, or keeping the needle in your skin a few seconds longer.

2) Is it ok to throw used needles in the trash?



Sisi, 10 years old, type 1 diabetes

@ Miss Chen Hi Miss Chen, is it ok to throw used needles in the trash?



Miss Chen, Registered Nurse

@ Sisi It is dangerous to throw used needles in the trash.

- For those who may touch this trash, including your families, they may have an accident needle sticks, which is dangerous.
- It is necessary to throw used needles carefully and safely according to local regulations.

3. References:

Fit UK. FIT UK Forum for Injection Technique UK-The UK Injection Technique Recommendations.3rd Edition: 2015

Australian Diabetes Educators Association (ADEA) Clinical Guiding Principles for Subcutaneous Injection Technique. Canberra: 2017

Australian Diabetes Educators Association (ADEA).Learning how to inject insulin. Available online: https://www.diabeteseducator.org/docs/default-source/legacy-docs/_resources/pdf/general/Insulin_Injection_How_To_AADE.pdf [Accessed 3/11/2018]

3.4 How to manage type 1 diabetes-insulin injection technology2

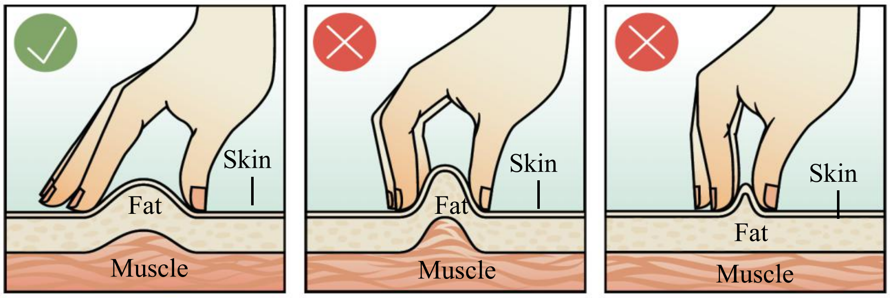
☆ **Key messages:**

- Pinching skin correctly and choosing appropriate needle can avoid injecting insulin into muscles.
- Never reuse your needles to inject insulin.
- Avoid lumps and bruising caused by insulin injection.

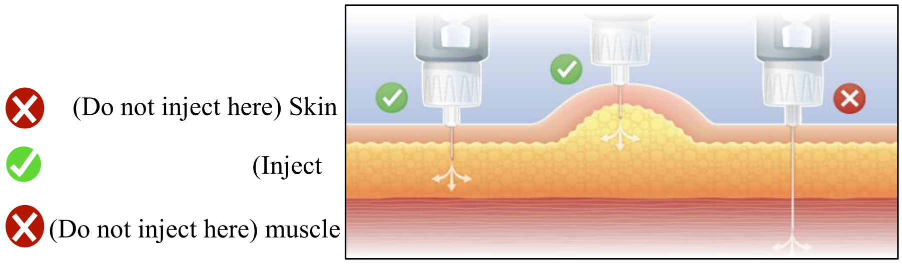
1. Introduction:

(5) How to pinch skin correctly

- This technology aims to reduce the risk to inject onto muscles.
- What could happen if I inject insulin into muscles? It could not only hurts but also results in much insulin uptake and low blood sugar.
- Only the thumb, index finger and middle finger should be used.

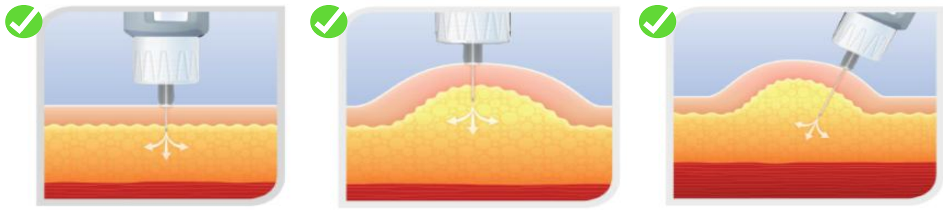


(6) Needle length



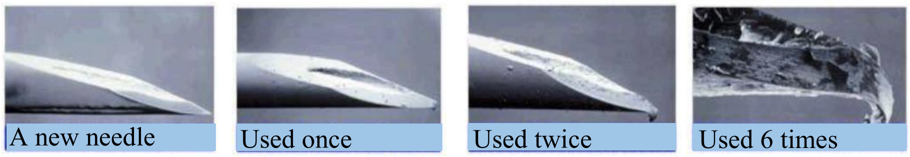
- If your needles are 5 mm or longer, your skin needs to be pinched.

- Injection angle: shorter needles can usually be injected at 90 degree, such as 4 mm. However, if you use longer needles, such as 5-mm or longer, 45-degree angle and pinched skin could reduce the risk to inject into muscles.



90° without punch-up　　90° with punch-up　　45° with punch-up

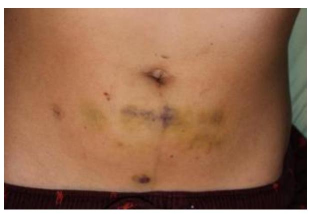
(7) Needle can only be used once. Reuse of needles could make you feel much more painful, and also cause infection and lumps in the injection sites.

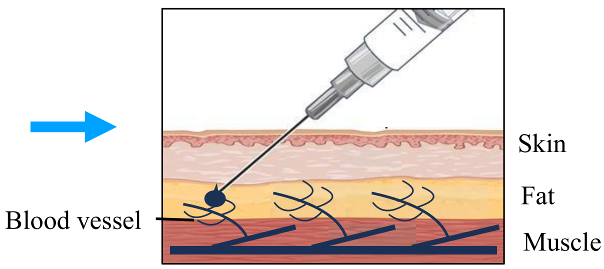


(8) Common side effects caused by insulin injection

1) Lumps usually are caused by repeated injection in the same point or using needles repeatedly.

2) Bleeding and bruising can be caused if needles went through some small blood vessels.



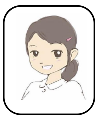


3. Frequently asked questions:

1) Are longer needles are better than shorter needles?

Kele, 17 years old, type 1 diabetes

@ Miss Chen Miss Chen, are longer needles are better than shorter needles?

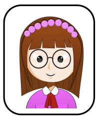


Miss Chen, Registered Nurse

@ Kele In almost all cases, shorter needles are better than longer ones.

- As mentioned above, insulin needs to be injected into fat layer. Needles that are at least 4 mm long can do the job very well.

2) How to prevent these side effects caused by insulin injection?



Sisi, 10 years old, type 1 diabetes

@ Miss Chen Hi Miss Chen, are there methods to prevent these side effects caused by insulin injection?

Miss Chen, Registered Nurse

@ Sisi Sisi, it's a good question.

- Actually, there are some methods to prevent these side effects, including injection site rotation and never reusing needles.
- Once these problems have happened, please tell your doctor or nurse.

3. A quiz (you can write your answers on the paper):

1) Where can you inject insulin into:

A. Muscle B. Skin C. Fat D. None at all

2) Reuse of insulin pen needle can lead to:

A. More painful to inject B. infection in injection sites C. Lumps D. All above

3) If there are lumps or bruising in an injection site, you can't:

A. Continue to inject in the site B. Inject in other sites C. Consult to your doctor or diabetes nurse

Note: Please find the answer at the end of this article.

4. References:

Fit UK. FIT UK Forum for Injection Technique UK-The UK Injection Technique Recommendations.3rd Edition: 2015

Australian Diabetes Educators Association (ADEA). Clinical Guiding Principles for Subcutaneous Injection Technique. Canberra: 2017

Australian Diabetes Educators Association (ADEA).Learning how to inject insulin. Available online:https://www.diabeteseducator.org/docs/default-source/legacy-docs/_resources/pdf/general/Insulin_Injection_How_To_AADE.pdf [Accessed 3/11/2018]

Answers to the quiz

The answers are "C, D, A". If you answered them correctly, congratulations! If not, do not worry, you can read the content repeatedly.

3.5 How to manage type 1 diabetes-blood sugar testing

☆ **Key messages:**

- Blood sugar testing is as important as insulin injection.
- For adolescents with type 1 diabetes, it is better to achieve values as close to normal as possible.
- HbA1c reflects the average blood sugar level in the past 8-12weeks.

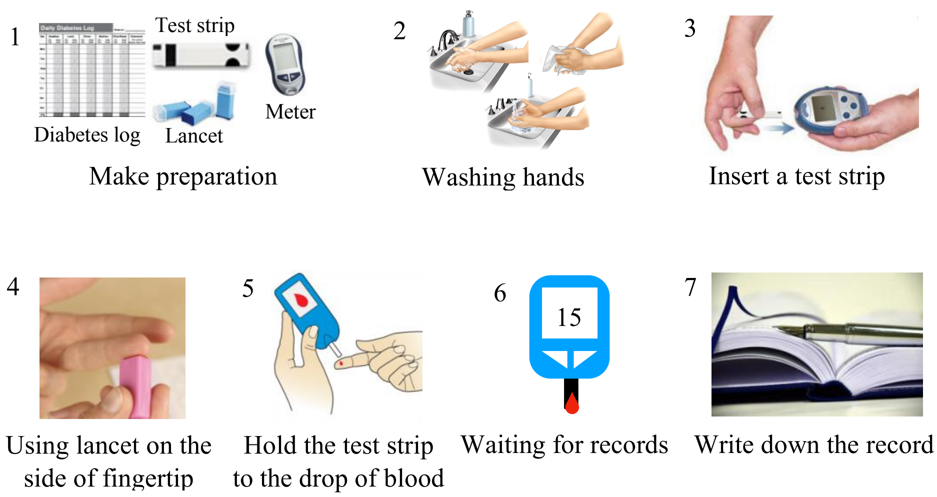
1. Introduction:

Many people with type 1 diabetes think there is no need to test blood sugar. Actually, blood sugar testing is as important as insulin injection. Take football for example. Insulin injection without blood sugar testing is like a blind people shooting in a football game. It is not easy to shoot because he can't see the goal.

• Three methods to test blood sugar: finger-prick test by people themselves, HbA1c test and a continuous glucose monitor (CGM).

(1) Test blood sugar by meter:

1) The process to test blood sugar by using meter:



2) Time points to test blood sugar:

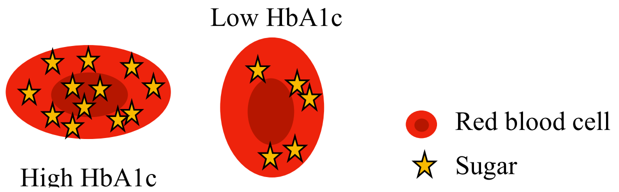
• Depends on doctor's suggestions.

3) Target of blood sugar for adolescents with type 1 diabetes:

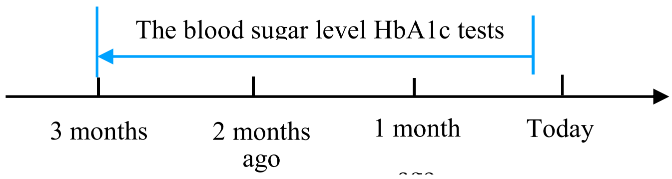
• Everyone should have their individual targets. Please ask your doctor about your blood sugar target and keep your target in mind.

(2) HbA1c test

• HbA1c refers to the sugar attached on the red cells.

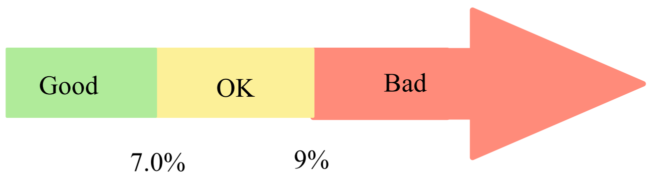


• HbA1c reflects the average blood sugar level in the past 6-12weeks.

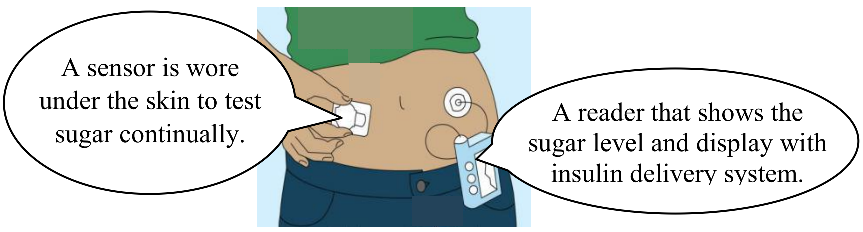


• Now, you can buy a special mentor to test HbA1c at home. If it's not available for you, you can also go to the hospital to have blood sample.

• For adolescents with type 1 diabetes, a target <7.0% is recommended to be optimal:



3) Continuous glucose monitor (CGM):



2. Frequently asked questions:

1) Blood sugar testing hurts. I tested my blood sugar when I feel sick.

Sisi, 10 years old, type 1 diabetes

@ Miss Chen Miss Chen, blood sugar testing hurts. I tested it when I feel sick.

Miss Chen, Registered Nurse

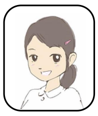
@ Sisi It is not correct to test blood sugar according to your feelings.

- Sometimes thought you do not feel sick, actually low or high blood sugar has happened.
- Blood sugar testing is hurt, however, it's a good way to keep your blood sugar stable.

2) I test my blood sugar regularly. I think HbA1c testing is not necessary for me.

Kele, 17 years old, type 1 diabetes

@ Miss Chen Miss Chen, I think HbA1c testing is not necessary for me because I test my blood sugar regularly.



Miss Chen, Registered Nurse

@ Kele Kele, it's not true.

- HbA1c need to be test once every 3 months.
- HbA1c provides an indiction of your average blood sugar in the recent 2-3 months.

3. A quiz (you can try to write down you answers on the paper):

1) About the blood sugar target among adolescents with type 1 diabetes, the RIGHT one is:

A. everyone has the same target with peers with type 1 diabetes

B. Everyone has different targets

C. Can be decided by adolescents themselves

2) HbA1c refers to the average blood sugar level in the past ________:

A. one month B. 2-3 months C. 6 months

3) Generally, for adolescents with type 1 diabetes, the HbA1c target needs to be:

A. <7.0 mmol/L B. 7.0-9 mmol/L C. >9mmol/L

Note: Please find the answer at the end of this article.

4. References:

Rewers, M. J., Pillay, K., de Beaufort, C., et al (2014) Assessment and monitoring of glycemic control in children and adolescents with diabetes. Pediatric Diabetes, 15 (Suppl. 20): 102-114

American Diabetes Association (2018) Check your blood glucose. Available online: http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/checking-your-blood-glucose.html [Assessed 31/10/2018]

American Association of Diabetes Educators (n.d.) Insulin injection know-how, pro tips (and tricks) for easier and better insulin injections. Available online: https://www.diabeteseducator.org/docs/default-source/legacy-docs/_resources/pdf/general/Insulin_Injection_Pro_Tips_AADE.pdf [Assessed 24/11/2018]

Answers to the quiz

The answers are “B, B, A”. If you answered them correctly, congratulations! If not, do not worry, you can read the content repeatedly.

☆ **Key messages:**

- Illnesses with fever can raise blood sugar, but with vomiting or diarrhea may lower blood sugar.
- When you are ill, more frequent blood sugar monitoring and insulin adjustment are important.
- If your blood sugar becomes too high to be uncontrolled, please do not hesitate to go to hospital.

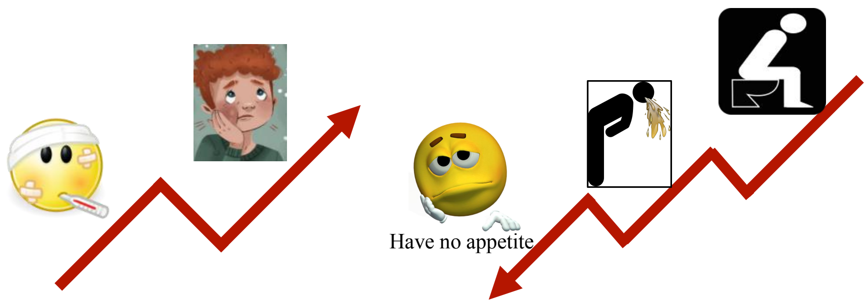
1. Introduction:

You may notice that your blood sugar becomes a monster and harder to be controlled when you are ill. You may want to know how your blood sugar becomes so changeable and what you can do.

(1) The effects of illness on diabetes

• The illnesses, which could cause fever, can raise blood sugar, such as cold or tooth infection.

• In contract, illness with vomiting, bowel movement or decreased food intake may lower blood sugar.



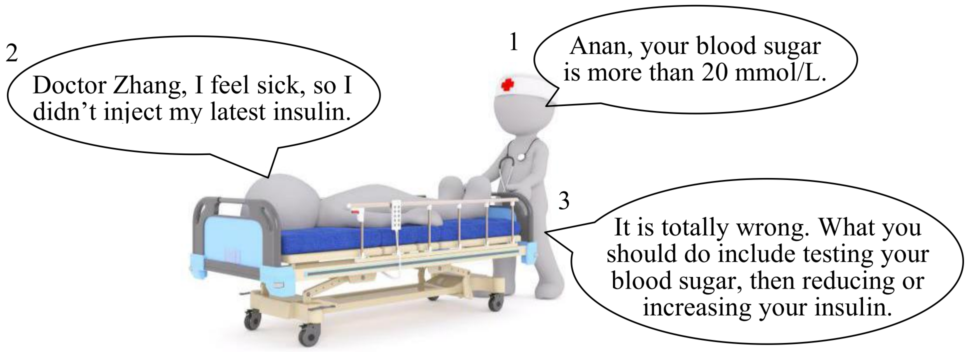
(2) Five general sick day diabetes management principles:

1) More frequent blood sugar monitoring:

• Blood sugar should be tested at least every 3-4h, sometimes every 1-2h, during illness.

2) DO NOT STOP INSULIN

• This is the most common mistake made by adolescents and their parents.



3) Maintain water balance

• Having a fever or infection could make you loss much water, which is why you need to drink.

• If you have no appetite, and your blood sugar is falling down 10 mmol/L, sugar-containing fluid need to be considered, such as diluted fruit juice.

4) Keep eating normally even if your blood sugar is high.

5) Insulin adjustment

• If you have a fever or infection, more insulin could be needed. If you vomit or bowel movement, less insulin may be needed. The specific regime from your doctor should be followed.

• Frequent blood sugar monitoring is important to provide evidence for insulin adjustment.

6) Go to hospital if your situation becomes uncontrollable

• If your blood sugar is still high, or serious vomiting or bowel movement cannot be stopped, please go to hospital as soon as possible.

2. Frequently asked questions:

- Why can't I stop insulin injection when I can't eat food?

Kele, 17 years old, type 1 diabetes

@ Doctor Li Doctor Li, why can't I stop insulin injection when I can't eat food?

Doctor Li, Doctor in diabetes

@ Kele Kele, it's a good question.

- Our body still needs to work when we stay there and do nothing.
- When you are ill, your body needs to work much harder, even if you don't eat food, that's why insulin is still needed.
- In terms of insulin dosage you need to inject, you should adjust it according to your blood sugar and doctor's suggestion.

3. **References:**

Brink, S., Joel, D., Laffel, L., et al (2014) Sick day management in children and adolescents with diabetes**.** Pediatric Diabetes, 15 (Suppl. 20): 193-202

Diabetes UK (n.d.) Diabetes and being ill. Available online: https://www.diabetes.org.uk/guide-to-diabetes/life-with-diabetes/illness [Accessed 5/11/2018]

3.7 How to deal with the relationships with schoolmates at school

☆ **Key messages:**

- It is you who can make the decision if you tell your schoolmates or friends about your diabetes.
- Teachers have the ability to take care your health when you are at school.

1. Introduction:

For people with type 1 diabetes, you may hesitate if you can tell friends about your diagnosis with diabetes, or you feel distressed about your relationship with your friends. Here are some discussions and from adolescents and suggestions from doctor.

1) Should I tell my friends or peers about my diabetes? How will they treat me?

Hi, I am Sisi and I was diagnosed with type 1 diabetes last week. I don't intend to tell my schoolmates about my diabetes.

Hi, I am Xiaoxue and I've been diagnosed for 1 years. @ Sisi Sisi, why don't you tell your schoolmates about your diabetes?

I don't want them to feel like that I am different.

Besides, some of their behaviours may make me feel sad if I tell them, because my schoolmates have no knowledge about diabetes.

Some of them may believe that diabetes is contagious and they would not to go close to me or touch me anymore. I could be labelled as diabetes and be isolated.

I also worry that they would spread my disease "all over the world" and make me receive extra attention, which is not what I want.

It makes sense, Sisi. Please don't forget the benefits for you to tell peers about your disease.

It is also a chance for your peers to care about you, such as sharing diabetes information with you, and care your feelings about the inconvenience of self-care and food restriction.

Someone even can act as "gatekeepers" to remind you to perform required self-care.

Moreover, peers can give you a hand when you are in emergency situations, such as coma.

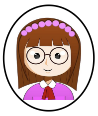
Hi, I'm Doctor Ma, a psychologist. This is a common puzzle for most adolescents with diabetes. All what you said make sense.

Actually, it is you who can make the final decision if you tell others or who you can tell. Maybe it's ok to tell somebody you can trust.

@Doctor Ma It is a good idea, Doctor Ma. I am Kele and was diagnosed last month. What can we do if we are bullied by others at school because of our diabetes?

Kele, please don't hesitate to do something to protect yourself, such as telling them you feel hurtful. If they don't stop doing that, please tell your teachers and parents.

2. Is it necessary to tell your teachers about your diabetes?



I think I will tell my headteacher. She is kind and it is safe to tell her about my diabetes.

Sisi, I agree with you. It is much safe for us if our teacher can know we have diabetes.

If you feel free, it is good to let your teachers know your diabetes and support your medical conditions at school. They can also deal with your emergency at school.

2. References:

Davidson, M., Penney, E. D., Muller, B.,et al (2004) Stressors and self-care challenges faced by adolescents living with type 1 diabetes. Applied Nursing Research, 17, (2): 72-80

Yang, P. Y., Lou, M. F., Lien, A. S. Y.,et al (2018) Adolescent Perceptions of Peer Responses to Diabetes Self-Management: A Qualitative Study. The Journal of Nursing Research, 26 (2): 104-111

Diabetes UK (n.d.) Diabetes in schools-responsibilities of headteachers, school governors& responsible bodies. Available online: https://www.diabetes.org.uk/Guide-to-diabetes/Your-child-and-diabetes/Schools/School-staff/Responsibilities-headteachers-school-governors-responsible-bodies [Accessed 1/11/2018]

SECTION 4

4.1 Diabetes complications and how to prevent—low blood sugar

☆ **Key messages:**

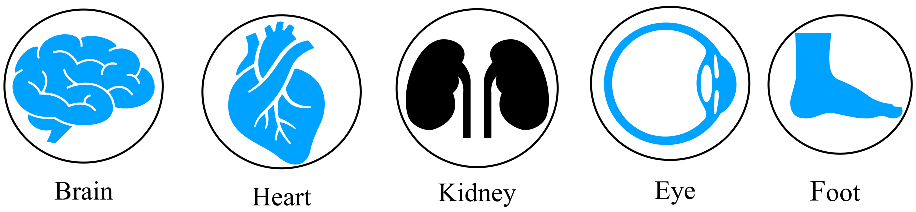
- Acute complications can happen suddenly.
- When blood sugar is less than 3.9 mmol/L, you may have feelings, such as feel hungry, high heartbeat, weakness, sweating and shakiness.
- If you experience low blood sugar, eat several sugar tablets or a spoon of honey immediately.

1. Introduction:

Have you experienced any complication? Maybe you haven’t, or you’ve experienced but you didn’t notice. It is necessary for you to know how to recognise, deal with, or even prevent complications.

• What is diabetes complications

For people with diabetes, their blood sugar could become too low or too high, which can seriously damage many parts of your body, including:



- Diabetes complications include acute (short-term) and chronic (long-term) complications.

(1) Acute (short-term) diabetes complications

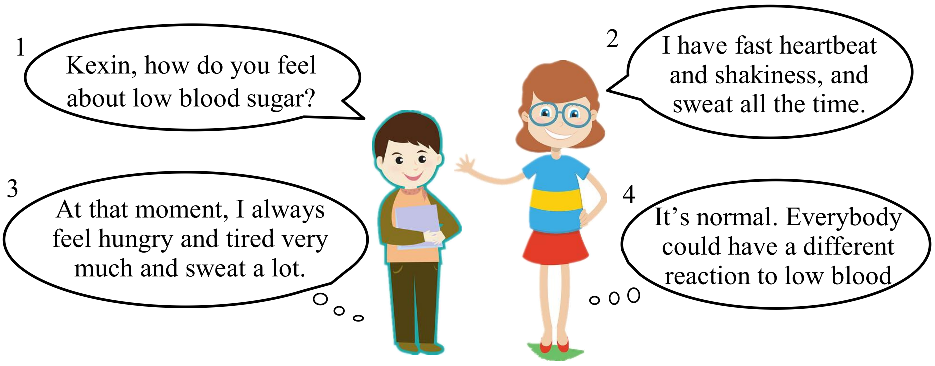
- Acute complications can happen suddenly, even before and short time after you are diagnosed.
- Acute complications include low blood sugar, high blood sugar and diabetic ketoacidosis (DKA).

1) Low blood sugar

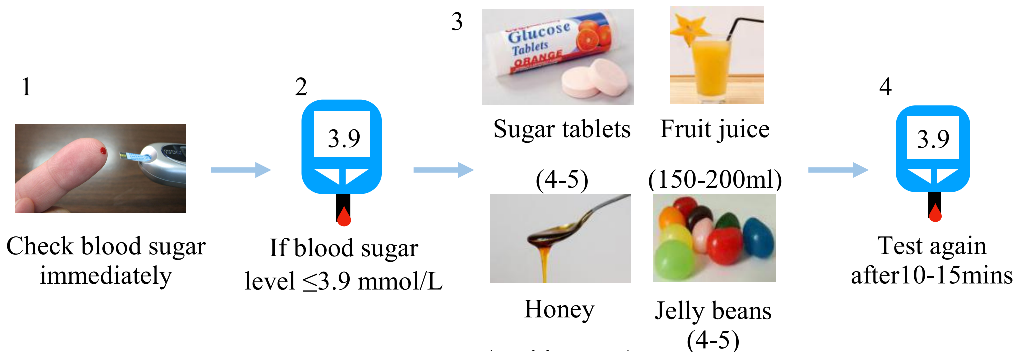
① A blood sugar level is too low, and less than 3.9 mmol/L, which is low blood sugar.

② Have you ever experienced some of following feelings:

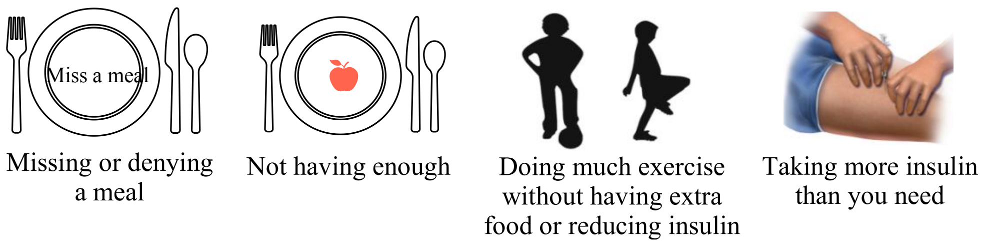
- If your answer is yes, at that moment, you would have LIKELY being experienced low blood sugar. However, everyone's experience about blood sugar is different. For example:



③ What you can do at that moment?



④ Why does it happen? The exact reason cannot be known, but somethings make it more likely:



⑤ How to prevent low blood sugar?

- Keep enough healthy food. Do not lose weight by missing meals.
- Take exact units of insulin. If you inject too much, telling your parents, doctor and frequent blood sugar are necessary.
- Before heavy exercise or exercise lasting more than 30 minutes, please increase food or reduce insulin according to doctor's suggestions.

2. A quiz:

1) If you are 15-19 years old with type 1 diabetes, you can try to write down the answers:

- Beibei is 15 years old and a-secondary-school student. He was diagnosed with type 1 diabetes last week. It is Wednesday and he is having a PE class. Suddenly, he feels not very good, dizzy, weakness and hungry, with high heartbeat and sweating.
- At this moment, what could happen to Beibei?
- If you were Beibei, what will you do?

Note: Please find the suggested answer at the end of this article.

2) If you are 10-14 years old with type 1 diabetes, you can have a try:

- Imaging that you are at school, and begin to feel hungry and shakiness with high heartbeat. You realise that you may have a low blood sugar. At this moment, what you can do?

Note: Please find the suggested answer at the end of this article.

3**. References:**

Ly, T. T., Maahs, D. M., Rewers, A., et al (2014) ISPAD Clinical Practice Consensus Guidelines – Hypoglycemia: Assessment and management of hypoglycemia in children and adolescents with diabetes. Pediatric Diabetes,15 (Suppl. 20): 180-192

International Diabetes Federation (IDF) (2018) KIDS diabetes information pack-a toolkit to inform on diabetes in school. Available online: https://www.idf.org/our-activities/advocacy-awareness/resources-and-tools/73:kids-diabetes-information-pack.html [Accessed 23/10/2018]

Diabetes UK (n.d.) What is Hypo? Available online: https://www.diabetes.org.uk/guide-to-diabetes/complications/hypos [Accessed 4/11/2018]

Suggested answers to the quiz:

① Beibei could have a low blood sugar.

② What you can do if low blood sugar happens:

- Don’t be shy to ask help from your classmates and teacher.
- Test blood sugar as soon as possible;
- If your blood sugar is lower than 3.9 mmol/L, eat some sugar or drink some juice immediately;
- Have a rest and test your blood sugar again after 10-15 minutes;

Note: If you answered them correctly, congratulations! If not, do not worry, you can read the content repeatedly.

☆ **Key messages:**

- DKA can be diagnosed according to blood sugar level, symptoms and blood sample test.
- When blood sugar is high, drinking lots of water and frequent blood sugar testing is essential.
- If your blood sugar is more than 33.3 mmol/L, or breath smells like rotten apple, please go to hospital immediately.

1. Introduction:

2) High blood sugar and diabetic ketoacidosis (DKA)

① The definition:

- High blood sugar means blood sugar is too high, and more than 11mmol/L.
- Blood or urine sample test could be done in the hospital to check if you have DKA, which is a kind of short-term and life-threatening complication.

② The symptoms:

- If you have some of following feelings, you could have a high blood sugar:

Very Thirsty


Need to go to toilet often


Easy to become angry


Stomachache

- If you have some of following experiences, you could have a DKA:


Deep, rapid breathing


Vomiting

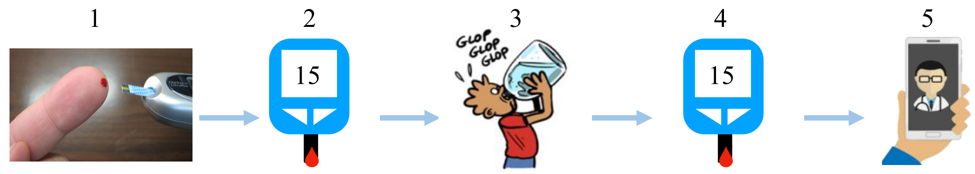

High heart rate


Abdominal pain


Breath smells like rotten apple


Consciousness reduction

③ What you can do at this moment?



Check blood sugar immediately | If blood sugar level ≥15 mmol/L | Drink lots of water to keep | 2 hours later, blood sugar level ≥15 mmol/L | Make call to your doctor

- If your blood sugar is more than 33.3 mmol/L, or your breath smells like rotten apple, please go to hospital immediately.

④ Why does it happen:

Missed insulin injection

Eat too much than you insulin can cope with

Fell stressed

Have a cold

Have an infection

⑤ How to prevent high blood sugar:

- Do not miss insulin injection and have appropriate amounts of food.
- Treat your cold or infection positively.
- Adjust yourself when you feel stressful.

2. A quiz:

1) If you are 15-19 years old with type 1 diabetes, you can try to finish this quiz:

- Kele is 17 years old and a secondary-school student. He was diagnosed with type 1 diabetes last month. Recently, he has always felt stressful because of his exams. This day, he is feeling very thirsty, begins to vomit, and cannot drink. His breath smells like the rotten apple.
- At this moment, what happens to Kele?
- If you were Kele, what will you do?

Note: Please find the recommended answer at the end of this article.

2) If you are 10-14years old with type 1 diabetes, you can have a try:

- What would you do if your blood sugar is 20 mmol/L and, suddenly, your breath smells like the rotten apple?

Note: Please find the suggested answer at the end of this article.

3. References:

Wolfsdorf, J. I., Allgrove, J., Craig, M. E., et al (2014) A Consensus Statement from the International Society for Pediatric and Adolescent Diabetes: Diabetic ketoacidosis and hyperglycemic hyperosmolar state. Pediatric Diabetes,15 (Suppl. 20): 154-179

International Diabetes Federation (IDF) (2018) KIDS diabetes information pack-a toolkit to inform on diabetes in school. Available online: https://www.idf.org/our-activities/advocacy-awareness/resources-and-tools/73:kids-diabetes-information-pack.html [Accessed 23/10/2018]

Suggested answers to the quiz:

① Kele could be have a DKA.

② What you can do if you realise you may have DKA:

- Ask help from teachers and classmates.
- Test blood sugar as soon as possible.
- Besides, ask them send you to the hospital immediately. At this moment, you are urgent because of high blood sugar, DKA and vomiting. Vomiting would let you dehydrate (lose too much water).

Note: If you answered them correctly, congratulations! If not, do not worry, you can read the content repeatedly.

4.3 Diabetes complications—chronic (long-term) complications

☆ **Key messages:**

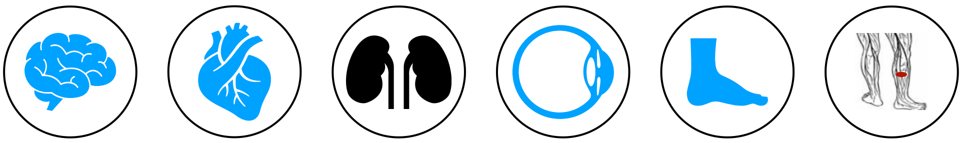
- Long-term diabetes complications develop gradually.
- Long-term complications are caused by blood vessels and nerves damage.
- Long-term complications are irreversible, therefore, prevention is the most important thing.

1. Introductions

Why do your parents and doctors care about your future after your diagnosis? What will happen if your blood sugar cannot be controlled well during a long period of time?

(2) Chronic (long-term) complications

- Long-term diabetes complications develop gradually and are irreversible.
- Too much sugar staying in the blood can damage blood vessels and nerve, which is why long-term complications happen.



Brain disease Heart disease Kidney disease Eye disease Diabetes foot Loss of sensitivity

1) Vessels problems in the brain and heart

- When blood vessels in the brain or heart are damaged, your heart or brain may have diseases.
- Heart and brain diseases are urgent and dangerous. However, Heart and brain diseases can be reduced or avoided if you can control your blood sugar well.

2) Kidney disease caused by type 1 diabetes

- In the very early stage of kidney damage, maybe you cannot feel unwell. As kidney disease becomes worse and worse, people can feel very sick:

Urinate less

Swelling feet and ankles

Feel tired

Loss of appetite

Vomit

Headache

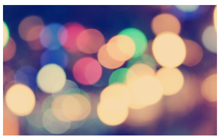
Itching

- Kidney disease is dangerous, which can be reduced or avoided if your blood sugar can be controlled well.

3) Eye disease caused by type 1 diabetes

- There is a part in our eyes named retina, which take charge of seeing.

- Lots of important vessels provide blood to our retina so that we can see something in front of us.
- However, when these vessels are damaged by diabetes, your sight will be affected. You may have:



Blurred version

Cloudy

Black marks

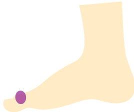
Blind

- If your blood sugar levels can be controlled well, eye complications can be reduced or avoided.

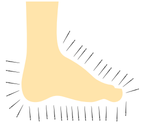
4) Diabetic foot and nerve damage caused by type 1 diabetes

- Raised blood sugar can damage your blood vessels and nerves around your feet, which is why you have higher risk of feet problems.


Wound cannot heal


Changes in colour


Feel like ants crawling


Feel like needling on feet


Cannot feel pain

- If you can control your blood sugar very well all the time, diabetic feet and nerve damage can be reduced or avoided.

2. Frequently asked questions:

1) I believe diabetes complications will not happen to me.


Kele, 17 years old, type 1 diabetes

@ Doctor Li Doctor Li, I believe diabetes complications will not happen to me.


Doctor Li, Doctor in diabetes

@ Kele Kele, prevention of these complications is the most important thing for you.

- For people with type1 diabetes, the higher their blood sugar levels are, the longer they have diabetes, the greater risk of complications they would have.
- Therefore, controlling blood sugar is the key issue, which will be mentioned next time.

2) If the complications will come to me sooner or later, it seems to be all in vain for me to control my blood sugar, which is not easy.


Sisi, 10 years old, type 1 diabetes

@ Doctor Li Hi Doctor Li, if the complications will come to me sooner or later, it is all in vain for me to control my blood sugar, which is not easy.


Doctor Li, Doctor in diabetes

@ Sisi Sisi, do not feel so negative.

- It is possible for people with type 1 diabetes to postpone or prevent complications.
- Blood sugar controlling is the most important thing.

3. References:

Donaghue, K. C., Wadwa, R. P., Dimeglio, L. A., et al (2014) Microvascular and macrovascular complications in children and adolescents. Pediatric Diabetes,15 (Suppl. 20): 257-269

Diabetes UK (n.d.) Complications of diabetes. Available online: https://www.diabetes.org.uk/guide-to-diabetes/complications [Accessed 13/10/2018]

☆ **Key messages:**

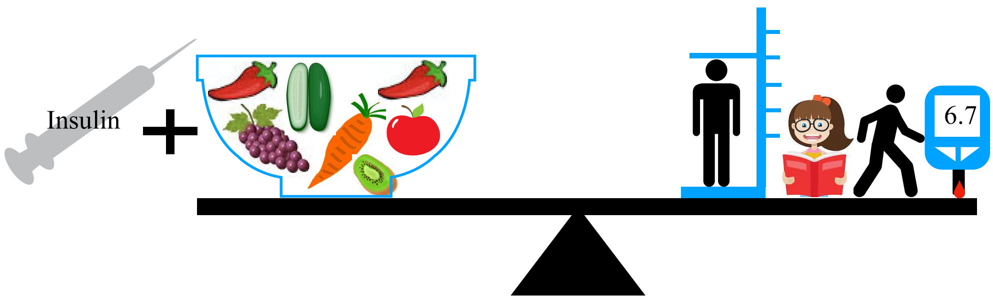
- Regard diabetes as your friend rather than enemy, and learn to live together with it.
- Healthy food, regular exercise, insulin injection and blood sugar testing are still the core.
- Regular physical check can help doctor recognise your complications in time.

1. Introduction:

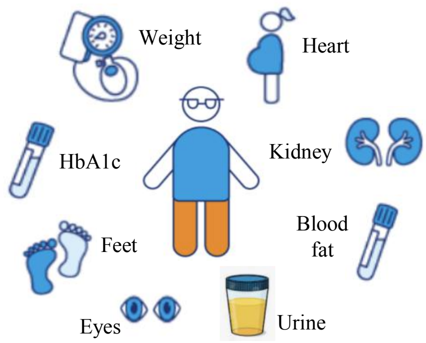
You may feel upset and distressed after knowing about long-term complications. However, the good news is that long-term complications can be prevented or postponed.

5) How to prevent long-term complications

- Long-term complications occur because continuous high blood sugar, or with going up and down, can damage blood vessel.
- Therefore, keeping your blood sugar close to normal as much as possible is the key.
- The method to prevent long-term complications is easy to say and difficult to do. It is important to regard diabetes as your friend rather than enemy, and learn to live together with it.
- Healthy food, regular exercise, insulin injection and blood sugar test are still the core to prevent long-term complications.



- Long-term damage is gradual. Regular physical check can help doctor recognise your complications on time.



6) Tips to take care of your eyes

- It is possible for most people to slow down or prevent eyes problems become worse, and blood sugar controlling is the key.
- Regular eyes screening is vital for doctor to recognise your eye problems on time.

Regular eyes screening

7) Tips to take care of your feet

- Check your feet every day. Whether you're going to put your socks on, or you're taking them off before bed, have a good look at your feet.
- Watch out cutting your nails. Cut them not too short. Trim them with nail clippers and then use an emery board to file any corners.

- Washing daily is also a simple way to keep your feet and toenails clean and away from infection. Water needs to be warm, not hot or cold.
- Make sure your shoes and socks are not too tight or loose.




- Use Cream to keep your feet moisturise.




- If you've lost any feeling in your feet, do not put your feet close to fire, hot or cold water, or hot-water bag.


2. A quiz (You can write down your answers on the paper)：

1) The keys to prevent long-term complications:

A. Diet B. Exercise C. Insulin injection D. Blood sugar testing E. All above

2) The best way to take care of your feet:

A. Look at and wash them every day B. Soak them for 1 hour each day

3) Numbness and tingling may be symptoms of:

A. Nerve damage B. Kidney disease C. Liver disease

Note: Please find the answer at the end of this article.

3. References:

Diabetes UK (n.d.) Diabetes and eye problems (diabetic retinopathy). Available online: https://www.diabetes.org.uk/guide-to-diabetes/complications/retinopathy [Accessed 5/11/2018]

Diabetes UK (n.d.) Know the signs of a serious foot problem when you have diabetes. Available online: https://www.diabetes.org.uk/guide-to-diabetes/complications/feet/serious-foot-problem [Accessed 5/11/2018]

National Institute for Health and Care Excellence (2014) Annual diabetes checks among indicators proposed for latest NICE QOF menu. Available online:https://www.nice.org.uk/news/article/annual-diabetes-checks-among-indicators-proposed-for-latest-nice-qof-menu [Accessed 5/11/2018]

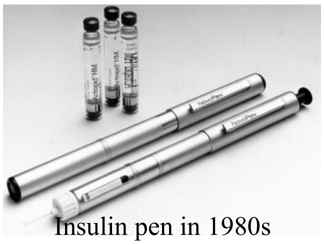
Answers to the quiz

The answers are “E, A, A”. If you answered them correctly, congratulations! If not, do not worry, you can read the content repeatedly.

4.5 Diabetes does not have to affect your future

I am Li Ming who live with type 1 diabetes for 60 years. My biggest success is that I control my blood sugar well and never let diabetes stop me from doing the things I'd love to do. I wish that my story can encourage young people with type 1 diabetes to be themselves.

I was diagnosed with type 1diabetes when I was 2 years old. In 1956, I had a dreadful mouth and tongue ulcers, then I began to drink lots of water and still felt thirty. I was took to see doctor, and sugar was found in my urine. Soon after diagnosed, I experienced my first low blood sugar and coma. However, I was so lucky because insulin had been developed when I was diagnosed with type 1 diabetes.


Insulin pen in 1980s

My first needles were used for long periods until they started to blunt and became more painful. Some people even used to sharpen their needles. Every Saturday morning, mum would boil my syringes and needles for 10 minutes and replace the disinfectant syringes. At that time, you can only test sugar in the urine at home, and know blood sugar vaguely by observing the change of colors on the strips. If you wanted to know exactly how much your blood sugar was, you needed to go to the hospital. Around 1980s, I began to use insulin pen and blood sugar meter, which was a big step forward.


My first strings

I appreciated that my parents were good at making sure type 1 diabetes didn't stop me from doing anything. They played an essential part in giving me a good start even so little support was available. They always encouraged me to be independent. I can still remember them getting me to inject into an orange and injected insulin by myself at an every young age.

Actually, diabetes management was not always going smoothly. Having type 1 diabetes means you need to pay more attention to your body and your blood sugar. I learned about carbohydrate counting, which can keep me eat appropriate amounts of food. I always insist on exercise. Going hiking is my favourite, and I also learn how to take care of myself outside. Never stop monitoring blood sugar and inject


Go hiking

insulin as type 1 diabetics. What I've learned from my life is: do not give up! Just keep trying to get your blood sugar under control as much as possible.

Some days are harder than others, but you just have to keep going. You just need to accept your type 1 diabetes and make it fit into your life. Over 60 years I've had type 1 diabetes, I've done everything I can to lead a full and exiting life. I had a successful and satisfied job, and I also encourage others with diabetes as a volunteer to be confident to live their own life.

When I was 18 years old, I met other several adults with type 1 diabetes when we went hiking. That exactly changed my attitude completely. We shared the same experience and could talk easily and openly, forming immediate bonds. And now I have so many close friends and contacts with the condition and we are regularly in touch. If you have type 1 diabetes, sharing your experiences with others with type 1 diabetes will make you feel supportive and encouraged.

Please remember that diabetes does not have to affect your future. Never give up.

References:

Diabetes UK (n.d.) "Advances to equipment and technology have been life-changing over the last 60 years". Available online: https://www.diabetes.org.uk/your-stories/type-1/ive-lived-with-type-1-diabetes-for-60-years [Accessed 5/11/2018]

Diabetes Research &Wellness Foundation (n.d.) Your stories about living with diabetes. Available online: https://www.drwf.org.uk/living-with-diabetes/your-stories [Accessed 5/11/2018]

Appendix 9: A letter to invite you to read a new diabetes material (readability test)

Dear ***,

If applicable, you can discuss the information below with your parent or family member:

1. Why am I receiving this?

- You are being invited to read a diabetes booklet, which is newly developed.

2. Why am I being asked to take part in?

- 10-19 years adolescents without diabetes are needed to figure out if you can understand this booklet.

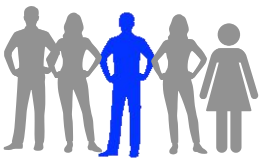
3. What is the booklet about?

- It is an interesting diabetes education booklet.
- It includes a cartoon story, interesting images and dialogue.

4. What do I need to do?

- Circle the word, phrase or sentence you can't understand.
- Write down your suggestions in the "Suggestion page" (with parents' help if applicable).

5. When and how to return?



- Two weeks are available for you.
- Please return the booklet to Mr Yang who is a teacher in your school.

6. Who do I work for?

Xiaolei Zhao
(A Nurse in the Affiliated Hospital of Southwest Medical University)

Thank you for your contribution to this diabetes booklet. Your private information will not be needed. If you and your parent have any future question, please contact 18208317865.

Best wishes

The researcher (Xiaolei)

Appendix 10: The evaluation form and informed consent for experts

Dear expert,

Thank you for helping with my PhD thesis, your time is greatly appreciated. There are 3 sections in this document, and the evaluation form and informed consent below need to be send back to Xiaolei through Email zhaoxiaolei8866@163.com. Many thanks.

1. Instruction:

Please review each topic of the educational material and provide an opinion on the accuracy of the content. After reading every topic, please assess the three aspects of 17 topics below by using "YES", or "NO", or "Partially". If your answers is "NO" or "Partially", there is also a section "others" for your reasons or other comments.

Besides, if you have any suggestion about any part of a certain topic, or if you think anything is missing, please add comments in the material or write it down at the end of the evaluation form.

2. The evaluation form:

Items	Scientific and clinically accurate (Yes/No/Partially)	Consistent with the purpose to improve knowledge and confidence to manage diabetes (Yes/No/Partially)	Necessary to be kept in this material (Yes/No/Partially)	Others
Section 1: A story				
1. Xiaobei's A day with type 1 diabetes				
Section 2: What is diabetes				
1. How did you feel about diagnosis				
2. What is diabetes				
3. Type 1 diabetes				
4. How does type 1 diabetes make you feel				
Section 3: How to manage type 1 diabetes				
1. knowledge and food				
2. exercise and insulin treatment				

Items	Scientific and clinically accurate (Yes/No/Partially)	Consistent with the purpose to improve knowledge and confidence to manage diabetes (Yes/No/Partially)	Necessary to be kept in this material (Yes/No/Partially)	Others
3. insulin injection1				
4. insulin injection 2				
5. blood sugar testing				
6. How to manage diabetes when you are ill				
7. How to deal with the relationship at school				
Section 4: Diabetes complication and how to prevent				
1. Low blood sugar				
2. High blood sugar				
3. Long-term complications				
4. long-term complications prevention				
5. Diabetes does not have to affect your future				
Any other suggestions or comments are welcome:				

3. An informed consent to acknowledge your role in my work:

Dear expert,

I would like to acknowledge your role in my work, which will include the thesis and potential scientific publications. Could you please provide me with consent to name you in my work?

If yes, please mark "Yes" option as red colour, such as "Yes, I agree"
If no, please mark "No" option as red colour.
Yes, I agree. No, please don't mention my name in your work.

Thank you for your hard working.

Appendix 11: Three scales selected or developed in this study (in English/Chinese)

Type 1 Diabetes Knowledge Scale

(Developed for 10-19-year adolescents with type 1 diabetes)

Tips

All the items only have one correct answer. Please read each one carefully and give your answer.

1. What is type 1 diabetes?

A. The body cannot produce sugar and lacks energy as a result.

B. The body nearly cannot produce insulin.

C. The body cannot use insulin properly.

2. Type 1 diabetes is a condition that

A. Can be cured with tablets or insulin.

B. Can be cured by adapting lifestyle.

C. Currently cannot be cured, but can be managed well.

3. Which of these is not a typical symptom of type 1 diabetes?

A. Obesity

B. Always thirsty

C. Always hungry

4. HbA1c reflects the average blood sugar levels

A. At the day when I have blood test

B. In the past week

C. In the past 8-12 weeks

5. Which of the following statements about type 1 diabetes and diet is true?

A. People with type 1 diabetes can eat sugar free diet without limitation.

B. People with type 1 diabetes cannot eat any fruit at all.

C. A diet which is low in fat, high in fibre, and low in sugar suits for everyone with type 1 diabetes

6. How often should people with type 1 diabetes like you who have no serious complication do exercise?

A. 3-5 days a week for at least 30 minutes

B. Once a week for at least one hour

C. Once a month for 2 hours

7. Why are people with type 1 diabetes like you advised to test the blood sugar?

A. To alert you to change in blood sugar levels

B. To help you make right decision at some special time, such as exercising, treating low or high blood sugar

C. Both of them

8. Which of the following statement about insulin storage and injection is FALSE?

A. Unused insulin should be stored in a freezer (<0℃), and once opened, insulin can be kept at room temperature (<25℃).

B. Before lunch you realised that you forgot to take your insulin at breakfast, you should check your blood sugar to decide how much insulin to take.

C. Rotation of injection sites are important in different areas, such as abdomen, front and lateral thigh, and also important within the same area.

9. What should people with type 1 diabetes like you do if you become ill (e.g. cold, infection)

A. Check blood sugar level more frequently

B. Stop taking insulin

C. Try to do as much exercise as possible to lower blood sugar levels

10. If people with type 1 diabetes like you have a low blood sugar (<3.9mmol/L), you should:

A. Immediately take some insulin

B. Have a rest until she/he feels better

C. Immediately have some sugar food or drink (e.g. fruit juice, honey)

11. Which of the following statement about diabetic ketoacidosis (DKA) is FALSE?

A. When you have the symptom of vomiting, deep sighing breath, breath smell like rotten apple, or even coma, you may be experiencing DKA.

B. Maybe DKA can happen to people like you if you inject excess insulin and eat less food.

C. If you suspect yourself to have DKA, you need to test your blood sugar immediately, drink lots of water, or go to hospital as soon as possible.

12. Which of the following statement about diabetes check ups is FALSE?

A. Check-up of eyes, nerve, heart and kidney once a year in the hospital

B. Regular diabetes check-up can lower blood sugar.

C. Annual diabetes check-up can help your doctor spot the early signs of diabetes complications.

Self-Efficacy in Diabetes Management (SEDM)

★ **Tips**

How sure are you that you can do each of the following, almost all the time?

Ten numbers in the options have different meanings. Please select one number which you agree in each item. For example, you can select 10 if you are 100% sure that you can increase or reduce the dose of insulin according to how much you eat. You can select 6 if

1 2 3 4 5 6 7 8 9 10

Not sure at all — Completely sure

1. Adjust your insulin correctly when you eat more or less than usual

1	2	3	4	5	6	7	8	9	10

2. Choose healthful foods when you go out to eat

1	2	3	4	5	6	7	8	9	10

3. Exercise even when you do not really feel like it

1	2	3	4	5	6	7	8	9	10

4. Adjust your insulin or food accurately based on how much exercise you get

1	2	3	4	5	6	7	8	9	10

5. Talk to your doctor or nurse about any problems you are having with taking care of your diabetes

1	2	3	4	5	6	7	8	9	10

6. Do your blood sugar checks even when you are really busy

1	2	3	4	5	6	7	8	9	10

7. Manage your diabetes the way your health care team wants you to

1	2	3	4	5	6	7	8	9	10

8. Manage your diabetes even when you have too many things to do

1	2	3	4	5	6	7	8	9	10

9. Find ways to deal with feeling frustrated about your diabetes

1	2	3	4	5	6	7	8	9	10

10. Identify things that could get in the way of managing your diabetes

1	2	3	4	5	6	7	8	9	10

System (webpages) Usability Scale (SUS)

★ **Tips**

Please rate each of the items on a level of agreement.

Five numbers in the options have different meanings. Please select one number which you agree in each item.

1= Strongly disagree

2= Disagree

3= Uncertain

4= Agree

5= Strongly agree

1) I think that I would like to use this webpages frequently.

1	2	3	4	5

2) I found the webpages unnecessarily complex.

1	2	3	4	5

3) I thought the webpages was easy to use.

1	2	3	4	5

4) I think that I would need the support of a technical person to be able to use this webpages.

1	2	3	4	5

5) I found that the various functions in this webpages were well related to each other.

1	2	3	4	5

6) I thought that there were some contents which do not match with each other in this webpages.

1	2	3	4	5

7) I would image that most people would learn to use this webpages very quickly.

1	2	3	4	5

8) I found the webpages have too many functions, which lead to inconvenience to use.

1	2	3	4	5

9) I felt very confident using the webpages.

1	2	3	4	5

10) I needed to learn a lot of things before I could get going with this webpages.

1	2	3	4	5

1 型糖尿病知识量表 (Type 1 Diabetes Knowledge Scale)

（为 10-19 岁 1 型糖尿病患者开发）

★ **小贴士**

所有的题目都只有一个正确答案。请仔细阅读每一个题目，给出您的答案。

1. 什么是 1 型糖尿病？

A. 身体不能生产糖分，导致能量缺乏。

B. 身体基本不能生产胰岛素。

C. 身体不能合理地使用胰岛素。

2. 1 型糖尿病是一种（　　　　）状态？

A. 能通过药物或胰岛素治愈。

B. 能通过调整生活方式治愈。

C. 截止目前为止，不能被治愈，但能被管理好。

3. 下列哪一项不是 1 型糖尿病的典型症状？

A. 肥胖

B. 总是感觉口渴

C. 总是感觉饿

4. 糖化血红蛋白（HbA1c）反应（　　　　）的平均血糖水平？

A. 血液检测当天

B. 过去一周

C. 过去 8-12 周

5. 下列哪一个关于 1 型糖尿病和食物的陈述是正确的？

A. 1 型糖尿病患者能无限制吃“无糖食品”。

B. 1 型糖尿病患者不能吃任何水果。

C. 低脂、高纤维和低糖的饮食适合每一位 1 型糖尿病患者。

6. 如果 1 型糖尿病患者没有严重的并发症，推荐锻炼的频率是?

A. 每周 3-5 次，每次至少 30 分钟

B. 每周 1 次，每次至少 1 小时

C. 每月 1 次，每次至少 2 小时

7. 为什么 1 型糖尿病患者需要测量血糖？

A. 让我们警惕血糖水平的变化

B. 能帮助您在一些特殊时期做出正确的决定，例如锻炼、低/高血糖的治疗

C. 以上两个均正确

8. 下列关于胰岛素储存和注射的说法，哪一项是错误的？（新增）

A. 未使用过的胰岛素应保存在冰柜（<0℃)，正在使用的胰岛素可放在低于 25℃的室温。

B. 如果您在午餐前，突然意识到自己忘记注射早餐前的胰岛素，此时您应先测血糖，再根据血糖值决定胰岛素的注射剂量。

C. 胰岛素注射在不同部位之间的轮换，如腹部、大腿前外侧，和同一部位内的轮换都很重要。

9. 假如您生病了（如感冒或感染），您需要？

A. 更频繁地监测血糖

B. 停止注射胰岛素

C. 尽可能多地锻炼，以降低血糖

10. 假如您发生了低血糖（<3.9mmol/L），您应该：

A. 立即注射一些胰岛素。

B. 休息直到您感觉好一些。

C. 立即吃些含糖的食物或者喝一些含糖饮料（如橙汁，蜂蜜）。

11.下列关于糖尿病酮症酸中毒的说法，哪一项是错误的？（新增）

A. 当您出现呕吐、深快呼吸、腹痛、呼吸有烂苹果味，甚至出现昏迷，您有可能发生了糖尿病酮症酸中毒。

B. 如果您注射过多的胰岛素或吃的太少，您有可能会发生糖尿病酮症酸中毒。

C. 假如您怀疑自己发生了糖尿病酮症酸中毒，您需要立即测血糖，喝大量的水，尽快去医院。

12. 下列关于 1 型糖尿病患者定期复查的说法，哪一项是错误的？

A. 每年一次，到医院复查眼睛、神经、心脏和肾脏功能。

B. 规律的并发症检查能降低血糖。

C. 每年进行并发症的检查，能帮助医生及时发现早期并发症的征象

糖尿病管理自我效能量表 (Self-Efficacy in Diabetes Management)

★ **小贴士**

您一直**有多确定**，自己能完成下列每一项?

选项中的 10 个数字代表不同程度，请您选择一个符合自己情况的数字。例如：您 100%确定自己能根据吃的多少，增加或减少胰岛素的量，你可以选择 10；如果您有信心，但是只能 60%确定，您可以选择 6：

1 2 3 4 5 6 7 8 9 10

完全不确定 …… **完全**确定

1. 当您比平时吃的多或少一些时，您能正确调整胰岛素的量：

1	2	3	4	5	6	7	8	9	10

2. 当您外出吃饭时，能选择健康食物：

1	2	3	4	5	6	7	8	9	10

3. 即使您不喜欢，但仍坚持锻炼：

1	2	3	4	5	6	7	8	9	10

4. 能根据您锻炼的多少，准确调整胰岛素或者食物的量：

1	2	3	4	5	6	7	8	9	10

5. 如果您有任何关于糖尿病管理的问题，会告诉您的医生或护士：

1	2	3	4	5	6	7	8	9	10

6. 当您很忙时，仍坚持血糖监测：

1	2	3	4	5	6	7	8	9	10

7. 能按照您的健康管理团队的要求，管理糖尿病：

1	2	3	4	5	6	7	8	9	10

8. 当您有太多事情要做时，仍能管理好糖尿病：

1	2	3	4	5	6	7	8	9	10

9. 当您对糖尿病管理很沮丧时，能找到办法解决：

1	2	3	4	5	6	7	8	9	10

10. 能找到那些影响您糖尿病管理的因素：

1	2	3	4	5	6	7	8	9	10

系统（网页）可用性量表 (System (webpages) Usability Scale)

★ **小贴士**

请您对每一个题目的“同意程度”进行打分。

选项中的每个数字代表不同的意思，请您选择一个符合自己情况的数字：

1= 完全不同意

2= 不同意

3= 不确定

4= 同意

5= 完全同意

1) 我认为我愿意经常使用这个网页。

1	2	3	4	5

2) 我发现这个网页太过于复杂了，没有必要。

1	2	3	4	5

3) 我认为这个网页容易使用。

1	2	3	4	5

4) 我认为我需要一个技术人员的支持才能使用这个网页。

1	2	3	4	5

5) 我认为这个网页的很多功能能很好地关联在一起。

1	2	3	4	5

6) 我认为这个网页的内容有太多前后不一致的地方。

1	2	3	4	5

7) 我能想象得到，大部分人能很快学会使用这个网页。

1	2	3	4	5

8) 我认为这个网页功能太多，使用很不方便。

1	2	3	4	5

9) 我感觉自己很有信心去使用这个网页。

1	2	3	4	5

10) 我需要学习很多东西，然后才能很好的使用这个网页。

1	2	3	4	5

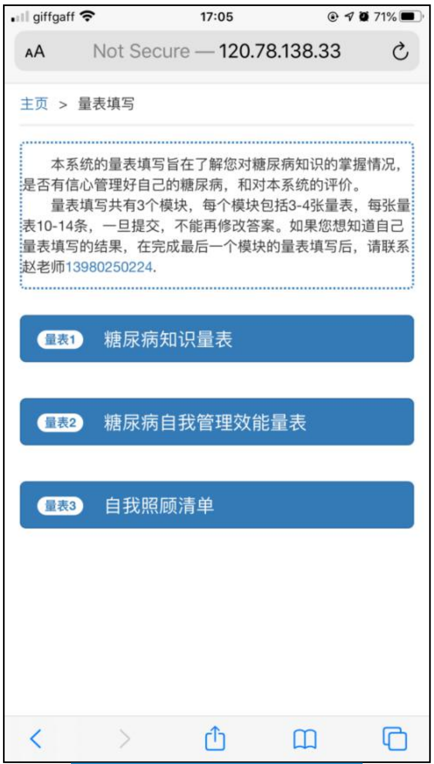
Appendix 12: The Chinese version of webpages screenshot

Users’ registration

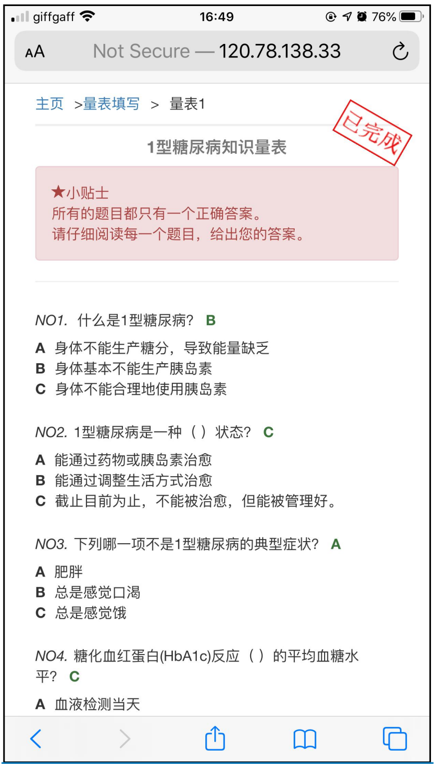
Log-in

Forget password

Home page



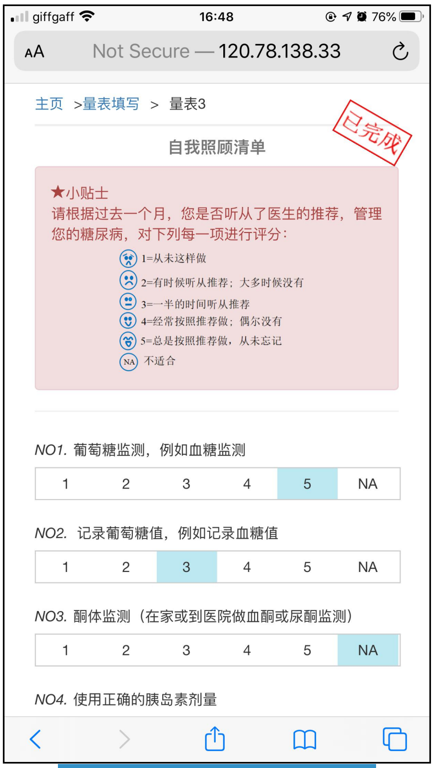
First “scale” part



Type 1 diabetes knowledge scale

Self-efficacy in

Diabetes management scale



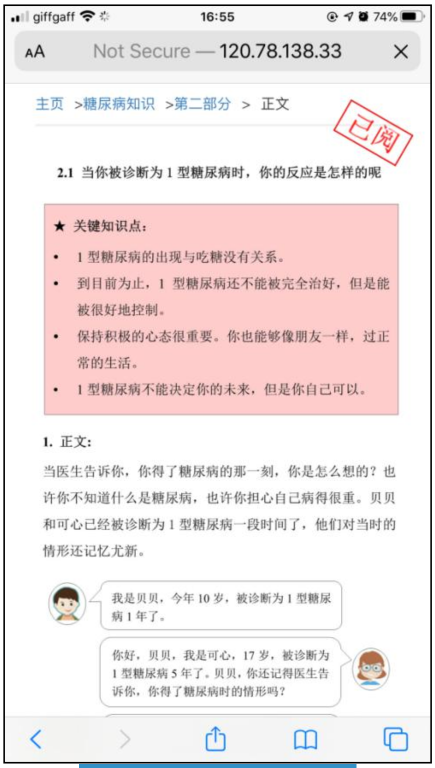
Self-care inventory scale

Four sections of

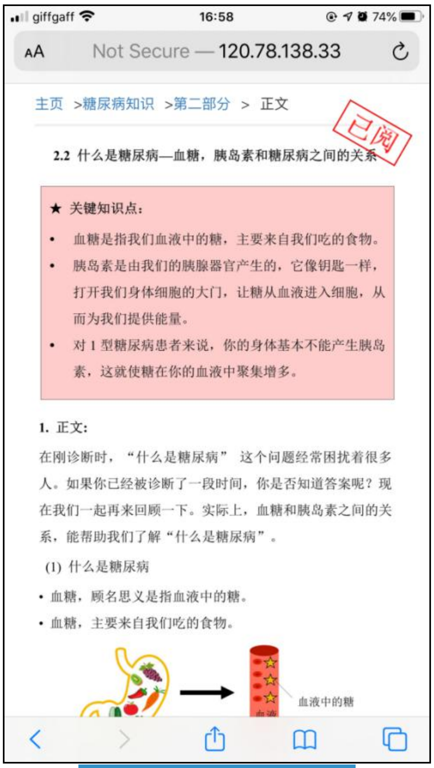
Introduction

Section 1

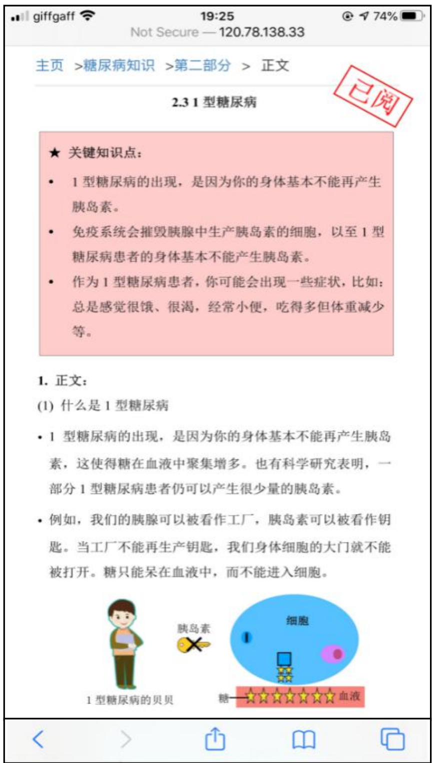
Section 2



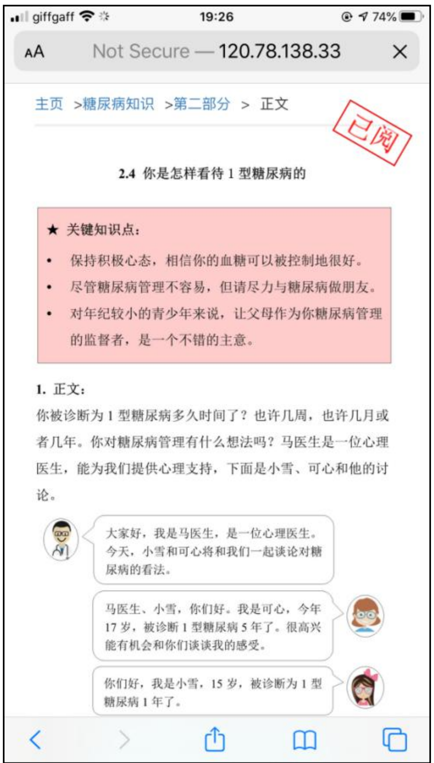
Section 2--2.1



Section 2—2.2

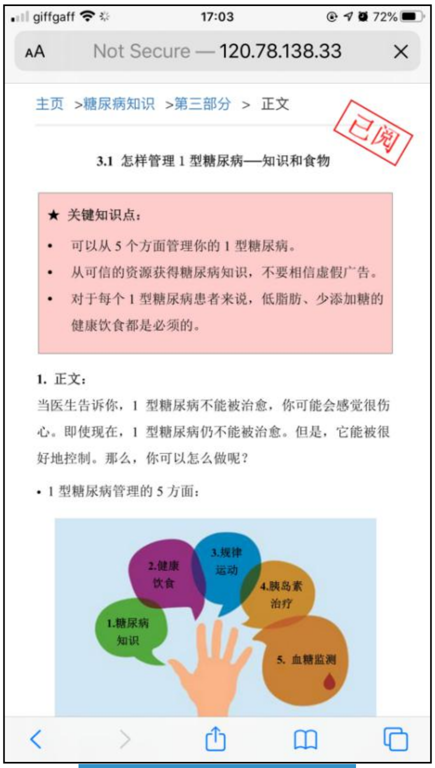


Section 2--2.3

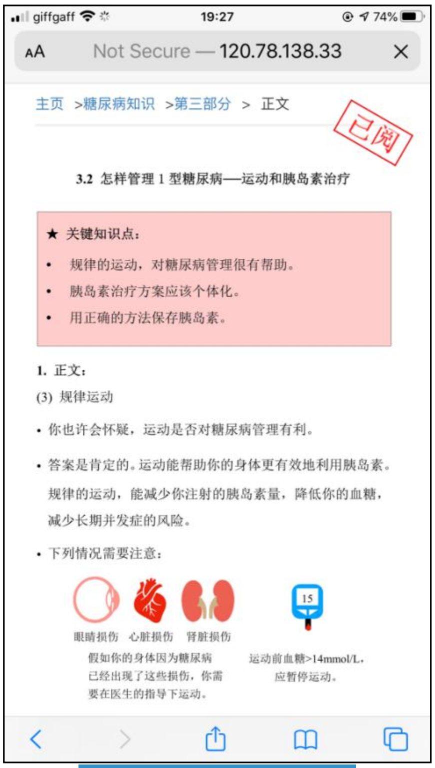


Section 2—2.4

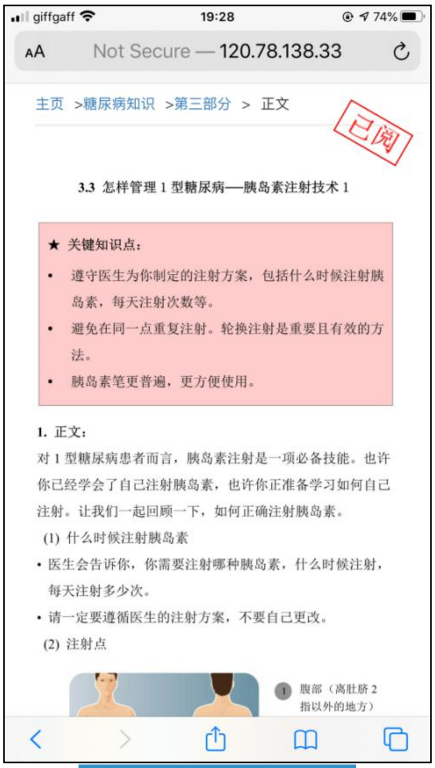
Section 3



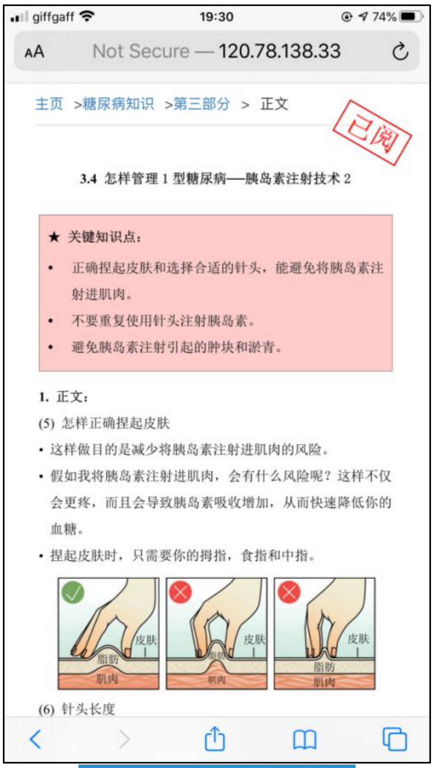
Section 3-3.1



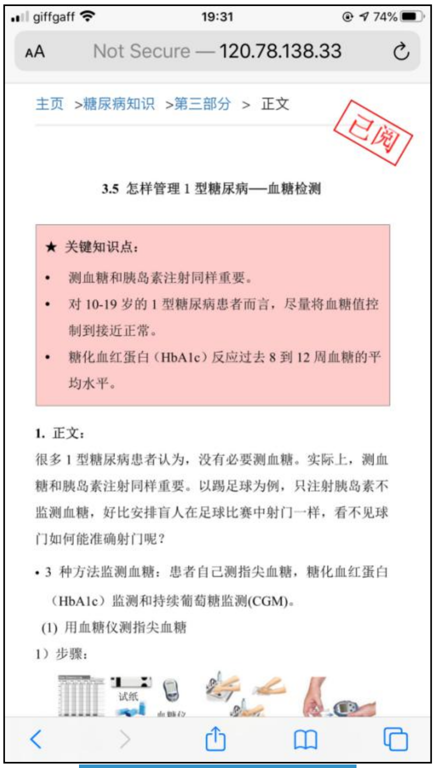
Section 3-3.2



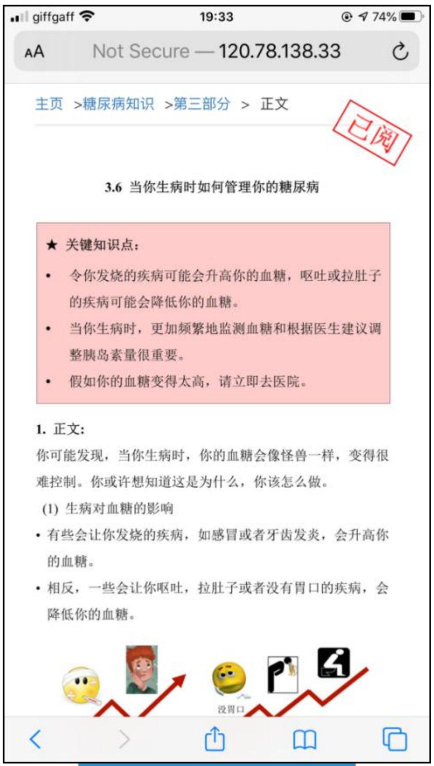
Section 3-3.3



Section 3-3.4



Section 3-3.5



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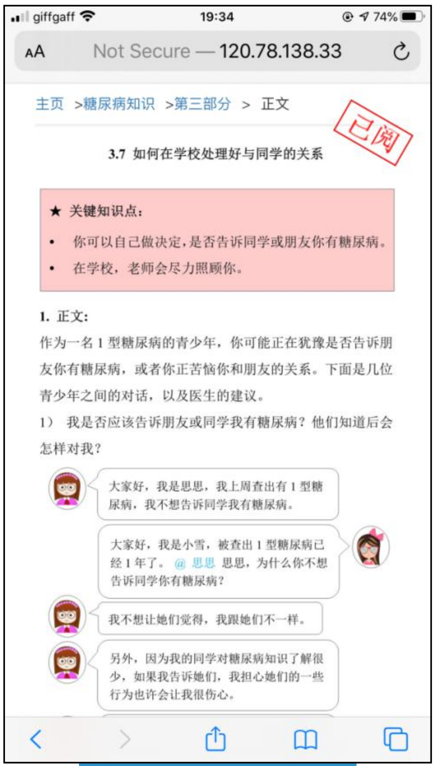
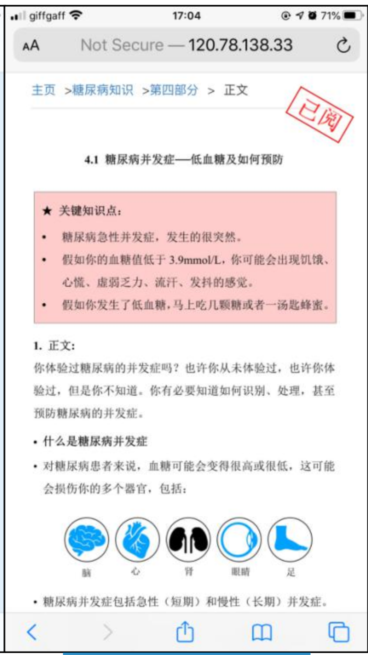
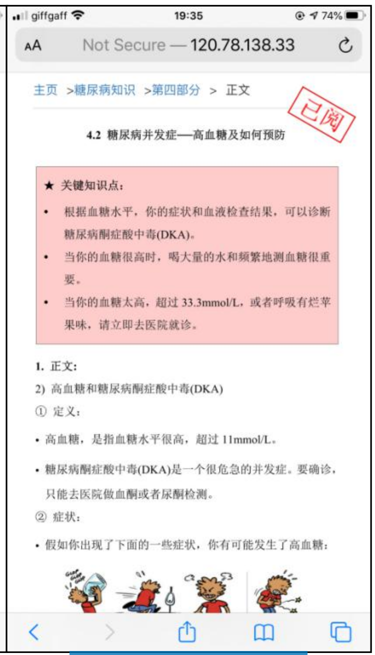


Section 3-3.7

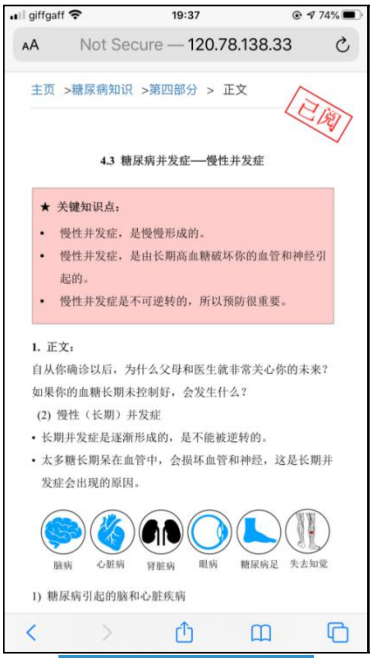
Section 4



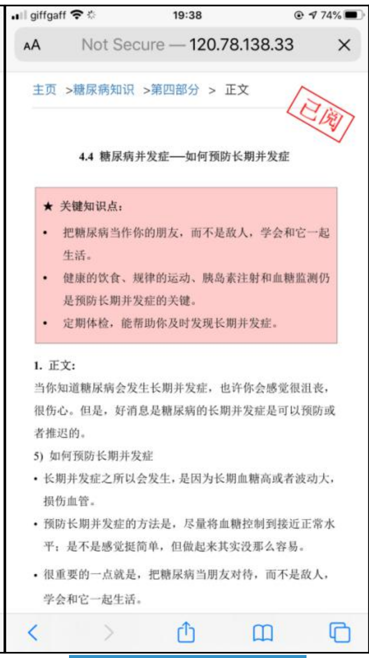
Section 4-4.1



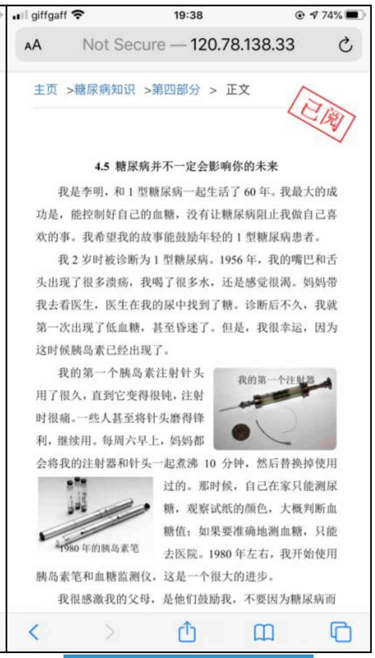
Section 4-4.2



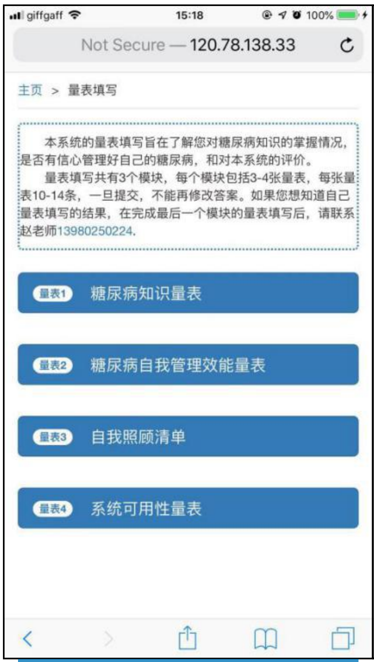
Section 4-4.3



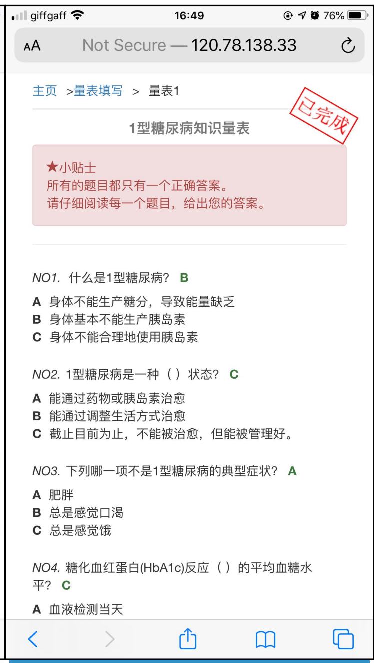
Section 4-4.4



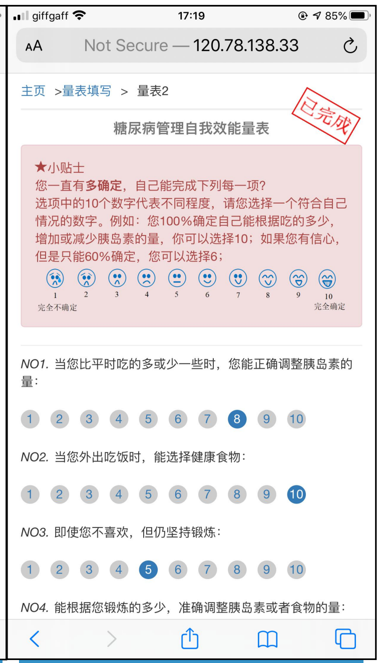
Section 4-4.5



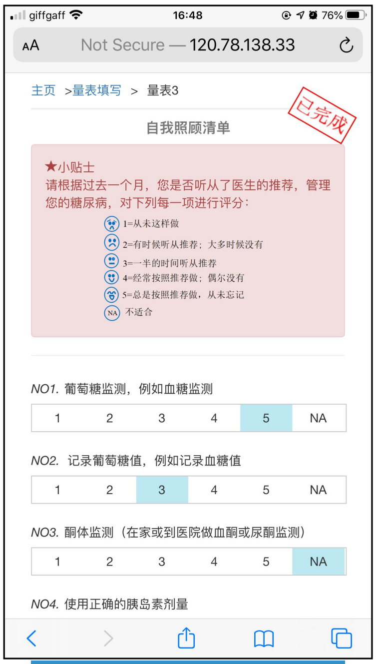
Second/third “Scale” part



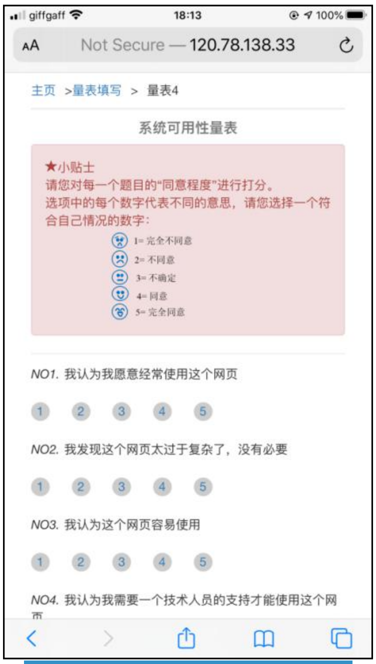
Type 1 diabetes knowledge



Self-efficacy in diabetes management



Self-care inventory



System usability scale