Development and Validity Testing of a Type 1 Diabetes Educational Material for 10-19-year Adolescents in China

Abstract

Purpose

The purpose of this study was to develop a Type 1 diabetes (T1DM) educational material for adolescents in China at the age of 10-19 years, and to test its validity for improving adolescents' diabetes knowledge, self-efficacy and adherence.

Methods

The study was carried out in four phases: preliminary development of the Type 1 diabetes educational material in English based on the health belief model (HBM) and the International Society for Pediatric and Adolescent Diabetes (ISPAD) Consensus Guidelines 2014; translation of the material into Chinese; readability testing of the material; and face and content validity testing for scientific and clinical accuracy.

Results

Type 1 diabetes educational material with 17 "topics" in four sections was developed for 10-19-year adolescents in China. Cartoon story, images, stories, questions & answers, and quizzes were used to attract adolescents' interest. Furthermore, the educational material was confirmed to be understandable among adolescents, clinically accurate, and consistent with its purpose.

Conclusions

This material with good readability and content validity is a potential facilitator for diabetes education and self-management in adolescents with T1DM in China.

Key words: Diabetes education; adolescents; Type 1 diabetes; self-efficacy; adherence

Type 1 diabetes (T1DM) is one of the most common metabolic diseases in adolescents globally, among whom poor adherence to therapy is a common concern.[1] Compared with adults with diabetes, adolescents are much further from achieving a A1C goal of <7%.[2-3] Suboptimal blood glucose with

chronic hyperglycaemia is associated with chronic diabetes complications, impaired prepubertal and pubertal growth, intelligence, and psychological difficulties among adolescent with T1DM. [4-5]

Evidence shows that educational interventions had small to medium beneficial effectiveness on blood glucose in adolescents with T1DM.[6-8] According to the International Society for Paediatric and Adolescent Diabetes (ISPAD) Clinical Practice Consensus Guidelines, education is the key to successful diabetes management, which could maximise the effects of diabetes treatment and the advances in diabetes management and technology.[9] Every adolescent with T1DM is recommended to receive quality assured structured education.[10]

In some western countries, such as the USA and UK, education as the center of diabetes management has developed into a structured, individualised, collaborative and ongoing process to support adolescents with T1DM to integrate self-management into their daily life.[11] In America, National Standards for Diabetes Self-Management Education and Support recommended that adolescents' characteristics should be considered in diabetes education and the curriculum should reflect current evidence.[12] In the UK, some structured diabetes education programs specifically for children and adolescents with T1DM were shown to be effective. For example, the KICk-OFF (the Kids In Control OF Food) program, a 5-day group education course in adolescents with T1DM, which focused on carbohydrate counting, insulin adjustment, and management of hypoglycaemia, ketosis and long-term complications.[13]

However, a gap still exists between those western countries and China in diabetes education and management among adolescents. In China, diabetes education has been treated as an optional supplement to medical treatment.[14] Limited diabetes education resources are available and tested scientifically in China. Existing diabetes material is difficult for adolescents to understand because of medical terms without appropriate explanation. In addition, there are no diabetes education materials specifically for adolescents with T1DM. Lack of easy-to-use diabetes material or brochures is considered by physicians to affect patients 'diabetes control.[14] Therefore, this study aimed to develop a type 1 diabetes educational material specifically for 10-19-year adolescents with T1DM in

China to improve their diabetes knowledge, self-efficacy and adherence, and to validate the Type 1 diabetes educational material.

Design, Methods and Results by Phase

This study was conducted in four phases. In phase I, the health belief model (HBM) and the ISPAD Clinical Practice Consensus Guidelines 2014 provided a theoretical framework and content outlines for preliminary development of the Type 1 diabetes educational material in English. During phase II, the WHO translation framework was used during the translation of the English material to Chinese. In phase III, readability was tested among adolescents to ensure that the material was understandable. During phase IV, face and content validity testing were conducted, where experts were invited to assess whether the Chinese material was scientific, clinically accurate, and consistent with its purpose to improve adolescents' diabetes knowledge, self-efficacy and adherence. The study was approved by the Faculty of Health Sciences (FHS) Research Ethics Committee in University of Hull and by the Ethics Committee of the Affiliated Hospital of Southwest Medical University in Luzhou, China.

Phase 1 (9/2018-12/2018): Preliminary Development of the Educational Material in English

This material was specifically developed for adolescents with T1DM aged 10-19 years in China, which aimed to improve their diabetes knowledge, self-efficacy and adherence. According to characteristics of the target population and the purposes of the material, basic principles of developing the educational material included: 1) the health belief model, diabetes guidelines and peer-reviewed publications provided a theoretical framework and references to ensure the material to be scientific and clinically accurate; 2) cartoon story, images, stories, questions & answers, and quizzes were used to make the material easy to understand and attract adolescents' interests; 3) some common psychosocial problems that adolescents would meet at home or school were also included in the material to improve adolescents' self-efficacy and adherence. Three steps were conducted in this phase:

Step 1 (9/2018-10/2018): Developing content outlines of the material

An important issue at this step was to ensure that contents of the material were comprehensive and systematic, and included basic knowledge that every adolescent with T1DM should know. The theoretical framework of the health belief model (HBM) and systematic education topics from the ISPAD Clinical Practice Consensus Guidelines 2014 compendium[15] made a major contribution to the content outlines of the T1DM educational material in this study. In addition, some psychosocial topics from peer-reviewed articles were also added. 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 content of the material was scientific and clinically accurate. Therefore, diabetes guidelines, such as the ISPAD guidelines which are specifically for children and adolescents with diabetes and "A toolkit to inform on diabetes in school" developed by the International Diabetes Federation (IDF),[16] association websites, such as the Diabetes UK and American Diabetes Association, and peer-reviewed articles were searched to provide references for every "topic". Totally, 24 "topics" with 70 pages (A4 sheet) were edited.

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

The contents were refined, including deleting duplicated contents and fixing the format of every "topic". Finally, 17 "topics" with 50 pages (A4 sheet) were retained 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".

Results

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

Only 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.[16] Tom's story described a day of Tom who was a boy with T1DM at school and home. However, people's characteristics, food and house style in Tom's story were based on some western countries, which were different from China and may cause confusion among Chinese adolescents. Therefore, Tom's story was adapted into a new Chinese cartoon story that was titled as "A day in the life of Xiaobei, living with type 1 diabetes". It described Xiaobei's meals, blood glucose monitoring, insulin injection and exercise on a school day. Xiaobei's story was designed by the first author (XLZ) and drawn by a first-year nursing student in the Southwest Medical University as shown in Supplemental Material 1.

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 conversations between presumed adolescents with T1DM. The presumed characteristics were set as Chinese persons who were also involved in the whole material. The presumed roles consisted of six adolescents at the age of 10-19 years, a nurse, a dietician, an endocrinologist, and a psychologist as shown in Supplemental Material 1.

The images and presumed characteristics in this material came from the internet and were re-edited to suit the material, which caused an essential issue, that was, copyright of the images from the internet. In order to follow the Copyright and Rights in Performance (Research, Education, Libraries and Archives) Regulations 2014 and respect the copyright-protected works, the images and presumed characteristics were searched from the 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 glucose check (a “topic”), “how to manage diabetes when you are ill” (a “topic”) and “how to deal relationship with schoolmates at school” (a “topic”).

Section 4: Diabetes complications and how to prevent

Five “topics” were developed, including low blood glucose and prevention (a “topic”), high blood glucose 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 living well with T1DM for nearly 60 years.

An important ethical issue occurred in this section. Some contents about complications in this material may frighten adolescents, such as retinopathy with potential blindness and neuropathy with risk of amputation. Taking the target population into consideration, the contents about potential severe diabetes complications were described positively, such as “If your blood sugar levels can be controlled well, eye complications can be reduced or avoided”.

Phase 2 (1/2019-3/2019): Translation of the type 1 diabetes education material

The T1DM educational material was originally developed in English because of two reasons. First, most references for this material were in English, which made it easier to edit English material; Second, content validity was also planned to be tested among experts in the UK as the first author was a PhD student in the UK. However, the material was developed for Chinese adolescents. Therefore, the English material was translated according to the WHO’s translation framework[17] through three steps:

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

According to the WHO’s translation guideline, the first author could be a suitable translator to perform the forward translation because she was a health professional and familiar with terms in this

material. The first author had lived in the UK for two years and had got to know the English-speaking culture. Her mother tongue is Chinese, which was the target language of the material. Therefore, the forward translation was conducted by the first author.[17] Some principles were insisted 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. [17]

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.[17] Considering this material had more than 50 pages, it was a challenge for one person to undertake the backward translation. Therefore, the material was divided into four parts and translated backwards into English by four colleagues of the first author. The four persons' mother tongue is Chinese, and their details (CT01-04) are presented in Table 1. 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 to the volunteers to complete the backward translation.

Step 3 (3/2019): Comparison between different versions of the material

This step aimed to check whether the Chinese version (CV) had precisely the same meaning as the original English version (EV1). The back translated version (EV2) was compared with the original English version (EV1) by the first author and two co-authors (AH & RW) who are native English speakers. The Chinese version was checked by the first author with EV1 and EV2. The differences between different versions were checked and modified to be consistent.

Results

At this phase, 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.

Phase 3 (3/2019-4/2019): Readability testing

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. A large gap was indicated between the required reading level to understand the health information and the actual readability among patients.[18] A readability gap was also reported between education materials and children's actual reading levels.[19] Therefore, readability testing of education materials cannot be emphasised enough.

In English, five readability assessment formulas 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.[20] 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 T1DM material was fairly easy to read. However, unlike in English, there have been no automatic tools with accurate prediction ability to test the readability of Chinese.[21] 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, which was described at following two steps:

Step 1 (3/2019): Adolescent recruitment

Adolescents between the age of 10-19 years old without diabetes were recruited to test the readability of the material because it was easier to recruit adolescents without diabetes than those with T1DM in China. As a result, seven adolescents without diabetes were recruited through a teacher who was working in a middle school in Luzhou. Details about the seven adolescents are presented in Table 2. To protect their privacy, their names are substituted by codes. Four (CA01-04) out of the seven adolescents were recruited from a school which was a combination of a primary school and a middle school. An informed consent 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 needed to do, and effects on adolescents. Permission of the readability testing was received from this school. Another three adolescents (CA05-07) who aged from 16 to 19 years were recruited separately and privately.

Step 2 (4/2019): Readability testing

After recruitment, every adolescent was given the printed material with an invitation letter and a "suggestion page". Considered their ages, the invitation letter was presented with images and simple words. The adolescents were asked to circle the word, phrase or sentence they could not understand by using a red marker, and write down their comments about advantages and disadvantages of the material in the "suggestion page". Two weeks were given to them to complete the readability testing. As a result, all seven adolescents completed the readability testing on time.

Results

(1) Readability of this material

Four adolescents did not mention any words or phrases of the material that they could not understand. Another three adolescents marked five medical terms which were difficult for them, including Type 1 diabetes, Diabetic ketoacidosis (DKA), A1C, Continuous glucose monitor (CGM), Long-term complications. However, no changes were made because the five medical terms were only marked before they read the definition or explanation of the terms. In addition, adolescents commented that 'medical terms were explained in easy-understanding ways' or 'there are no words or sentences which cannot be understood'.

(2) The characteristics adolescents liked in this material

Every adolescent wrote down the advantages of this material. Generally, adolescents evaluated that the material was easy to understand and interesting, which was summarised in two ways. First, the involvement of cartoon story, images, conversations and examples was warmly welcome. Some comments from adolescents are quoted: 'The cartoon story is simple and intuitive'; 'Images help me

understand the content'; 'The conversations between adolescents and doctors are good, including questions & answers'; 'Combination of words, images and cartoon story is easy to understand and would win kids' heart'; 'The content is comprehensive, and the format is good'; 'It is good to use examples to explain some abstract contents, which becomes not boring, but interesting and vivid'. Second, some specific contents which attracted adolescents were also mentioned: 'The contents about insulin injection at page 27 are good'; 'The advantages and disadvantages of diabetes (how to manage diabetes and complications prevention) were described clearly'; "I like the content about symptoms of diabetes'.

(3) Aspects of the material which required improvement

Some adolescents also gave their suggestions of the material, which were summarised and given corresponding solutions in Table 3. Some suggestions were feasible and adapted at this time. Some suggestions could provide good references for the reedition of the material next time.

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

For a newly developed tool, the psychometric properties need to be tested to identify whether the tool is reliable and valid to be used in a certain population.[22] Therefore, it was important to ensure that the new-developed educational material should be psychometrically sound. Face validity and content validity testing were conducted in this study. Face validity meant to test the grammar, organisation, appropriateness and confirm whether the material appeared to flow logically. Content validity was to test whether the contents were scientific and clinically accurate.[23]

Step 1 (3/2019): Recruitment of experts

Type 1 diabetes management is a comprehensive process for adolescents, in which diet and psychological management are important but difficult parts. 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 education material. Experts from the National Health Service (NHS) in the UK and a university hospital in China were invited. Finally, six experts

(CE01-02, CN01-02, CD01, CP01) from the Affiliated Hospital of Southwest Medical University in China agreed to participate in, whose Information was summarised in Table 4.

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

In the first-round testing, an invitation email, and an evaluation form with introduction, 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 send to the 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 phrases, they could comment on the educational material. Three weeks were given to the experts. The evaluation form and comments were returned on time by all six experts in the first round. In the second-round testing, according to suggestions from the experts in the first-round testing, the education material was reedited and sent to the six experts again. Three weeks were still given to them. As a result, five experts gave the further suggestions and another one had no more advice.

Results

(1) Evaluation of 17 "topics" from three aspects of the material

As shown in Table 5, first, in terms of the scientific and clinical accuracy, 11 "topics" and five "topics" were assessed to be or partly be scientific and clinically accurate, separately. 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. Second, 10 "topics" and 7 "topics" were assessed to be or partly be consistent with the purpose to improve diabetes knowledge and confidence to manage their diabetes, separately. Third, about whether it should be retained, all the "topics" were assessed as "yes" or "partly yes". Only the cartoon story in the first section was assessed partly to be retained because the insulin injection site on Xiaobei's abdomen was not accurate. All of 17 "topics" were retained after revision suggested.

(2) Suggestions and changes from the content validity testing

In the first-round testing, six experts gave their suggestions, and only five experts gave advice in the second-round testing. The practical suggestions were adopted as suggested. For example, in section 4.3 “long-term complications”, the expression ‘If your blood sugar levels can be controlled well, eye complications can be reduced’ was assessed by an expert (CE02) to be not accurate, which was changed into ‘If…, eye complications can be reduced or avoided’ as suggested. Some suggestions were not modified. For example, in section 4.1 "low blood sugar”, an expert (CD01) mentioned that the limit of low blood sugar should be 2.8-3.0 mmol/L (latest textbook of Internal Medicine in China), rather than 3.9 mmol/L. However, the ISPAD Clinical Practice Consensus Guidelines 2018 was checked. It was mentioned that blood glucose 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. Therefore, this advice was not adopted in this material. The educational material for adolescents with T1DM was finalised after modification. A part of the educational material is attached in Supplemental Material 1.

Discussion

Written educational materials are recognised as the backbone of comprehensive education programmes for people with diabetes. A systematic review indicated that written material interventions appeared to produce modest benefits in chronic disease management.[24] Compared with other education methods, written material is less costly and reusable, which provides participants flexibility to choose appropriate time and place for reading. In another systematic review, verbal education was reported to be less effective in improving knowledge and satisfaction in participants, compared with combination of written material and verbal education.[25] However, there had been no validated type 1 diabetes educational material for adolescents in China, which actively supported the development of culturally sensitive education material in this study.

According to the National Standards for Diabetes Self-Management Education and Support in America, target population’s characteristics, such as cultural background, age and perception of

diabetes, should be considered in diabetes self-management education services.[12] In this study, adolescents aged 10-19 years were receiving the formal education levels from primary school to university in China, which posed a challenge for the material development. However, the ISPAD guidelines and peer-reviewed articles were searched in this study to identify adolescents' needs of knowledge and their perception of diabetes at different age groups.

In addition, clarified learning objectives, up-to-date content, clear and direct layout, acceptable readability and easy-understanding illustrations were recommended to improve the quality of written education materials,[26-27] which was also the main structure of the Suitability Assessment of Materials (SAM) scale to assess the suitability of written health education materials.[28] In this study, first, the education purpose was explicit, which was to improve adolescents' diabetes knowledge, self-efficacy and adherence. Therefore, the material not only focused on diabetes knowledge, but also included physiological issues and common problems to affect adolescents' adherence. Second, the latest guidelines and peer-reviewed articles provided references for this material to ensure that the content was accurate and up-to-date. Third, the material was sent to experts to assess face and content validity, and the result showed that it was clinically accurate and scientific. Fourth, as far as layout, the material was edited in five fixed formats, which made it easy for adolescents to read. Subtitles were used in the material to motivate adolescents to read, as well as short paragraphs (one or two sentences in a line). Furthermore, the message should be written in active voice, rather than passive ways.[26] For example, the contents about potential diabetes complications were described positively, such as "If your blood sugar levels can be controlled well, eye complications can be reduced or avoided", which could encourage adolescents to follow their diabetes regimen.

In addition, most patient education materials were indicated to have higher reading levels than the readability of target populations. Specifically, 30-100% of educational materials were written at above the 8th grade level, however, participants could read at a 5th grade or higher level on average.[29] Different from English materials with mature tools to assess the readability, there was no effective tool to evaluate the readability of Chinese.[30] However, readability was tested in this study by

recruiting adolescents without diabetes at the same age group to comment, and the result showed that this material was understandable for 10-19-year adolescents. Those adolescents were also interested in the cartoon story, images and conversations between presumed characteristics, which played an important role in illustration of the material. The attractive illustrations were correlated closely and directly to the contents in the material, which could motivate adolescents to read further and help them understand abstract definitions or contents.

Although the material was tested to be understandable with good content validity, there are two aspects of limitations in this study. First, because of limited time and fund, the target population were not included during the development of the material. Second, the effectiveness of the material-based interventions is not assessed in Chinese adolescents with T1DM at the age of 10-19 years, which should be explored in a future trial.

Conclusion

It is feasible to develop a type 1 diabetes educational material for adolescents in China, which was tested to have a good readability and acceptable content validity. In addition, multiply illustrations, such as cartoon story, images and conversations, are beneficial to attract adolescents' interests and receive good reviews. However, the effectiveness of the material-based intervention needs to be explored further in a future trial.

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