Development of the Knee Injury and Osteoarthritis Outcome Score for Children (KOOS-Child)

Comprehensibility and content validity

Maria Örtqvist[1], Ewa M Roos[2], Eva W Broström[1], Per-Mats Janarv[1], and Maura D Iversen[3,4,5]

[1]Department of Women's and Children's Health, Karolinska Institutet, Stockholm, Sweden; [2]Unit for Musculoskeletal Function and Physiotherapy, Institute of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark; [3]Section of Clinical Sciences, Division of Rheumatology, Immunology and Allergy, Brigham and Women's Hospital; [4]Harvard Medical School; 5 Department of Physical Therapy, Northeastern University, Boston, MA, USA.
Correspondence: m.iversen@neu.edu
Submitted 11-12-11 Accepted 12-07-13

Background and purpose **The Knee Injury and Osteoarthritis Outcome Score (KOOS) is distinguished from other knee-specific measures by the inclusion of separate scales for evaluation of activities of daily living, sports and recreation function, and knee-related quality of life, with presentation of separate subscale scores as a profile. However, its applicability in children has not been established. In this study, we examined how well the KOOS could be understood in a cohort of children with knee injury, with a view to preparing a pediatric version (KOOS-Child).**

Material and methods **A trained researcher conducted cognitive interviews with 34 Swedish children who had symptomatic knee injuries (either primary or repeated). They were 10–16 years of age, and were selected to allow for equal group representation of age and sex. All the interviews were recorded. 4 researchers analyzed the data and modified the original KOOS questionnaire.**

Results **Many children (n =14) had difficulty in tracking items based on the time frame and an equivalent number of children had trouble in understanding several terms. Mapping errors resulted from misinterpretation of items and from design issues related to the item such as double-barreled format. Most children understood how to use the 5-point Likert response scale. Many children found the instructions confusing from both a lexical and a formatting point of view. Overall, most children found that several items were irrelevant.**

Interpretation **The original KOOS is not well understood by children. Modifications related to comprehension, mapping of responses, and jargon in the KOOS were made based on qualitative feedback from the children.**

When evaluating knee function in children suffering from a knee injury, it is imperative to measure both functional and patient-reported outcomes. The Knee Injury and Osteoarthritis Outcome Score (KOOS) (Roos et al. 1998b) is a self-administered disease-specific measure designed to assess patient-reported knee outcomes in adults with joint injury or degenerative disease. It addresses 5 domains including: pain, other symptoms, activities of daily living (ADL), sports and recreation (Sport/Rec), and knee-related quality of life (QoL). This instrument is highly reliable, valid, and responsive to change in subjects with knee injury (Roos et al. 1998a). Compared to other knee outcome measures such as the International Knee Documentation Committee Subjective Knee Form (IKDC) (Irrgang et al. 2001), the Tegner Activity Scale (Tegner and Lysholm 1985), and the Lysholm Knee Scoring Scale (Lysholm and Gillquist 1982), which result in a single total score, the KOOS produces 5 subscores (Roos et al. 2011). It includes separate subscales for assessment of ADL function and higher physical function in sports and recreation, and also a scale for knee-related QoL, which are not present in other means of measuring knee outcome. The original KOOS is available in 28 different language versions and is used in several international databases (Roos et al. 2011). The usability of the KOOS in adults has been demonstrated in several reviews (Garratt et al. 2004, Wang et al. 2010, Roos et al. 2011) and the KOOS has been shown to be highly reliable and valid when used in adult patients with different knee diagnoses and for different interventions, e.g. ACL injury, meniscectomy, cartilage repair, and total knee replacement (Roos and Toksvig-Larsen 2003, Roos et al. 2011). To our knowledge, the comprehensibility, reliability, and validity of the KOOS has not been assessed in children. We hypothesized that the original KOOS would require modification for use in a young population. Thus, this study was designed to evaluate the comprehensibility of the KOOS in children 10–16 years of age. The purpose was to gather information to modify

DOI 10.3109/17453674.2012.747921

the KOOS into a new children's version that would then be evaluated for psychometric properties (validity, reliability, and responsiveness) in a larger clinical study.

Material and methods

We conducted cognitive interviews with 34 Swedish children with a mean age of 14 (10–16) years, 17 of whom were girls. The most common diagnosis was anterior cruciate ligament injury (n = 11), followed by a mixture of diagnoses including patellar dislocation/instability (n = 5) and meniscal injury (n = 6). 16 of the 34 children had undergone knee surgery and 25 of them had been treated by a physiotherapist. Cognitive interview is the "gold standard" methodology for determining the flaws in survey items and for identifying sources of response error due to lack of comprehension of items (Willis et al. 1991, Tourangeau et al. 2002, Willis 2005). This technique has been effective in determining children's understanding of another knee outcome measure (Iversen et al. 2010). Here, the goal of each interview was to prompt subjects to explain the cognitive processes used to respond to survey items, to illustrate how information was retrieved from memory, and to identify comprehension of items and decision-making processes used to arrive at a specific response. This information was used to highlight the items that were difficult to answer and to make modifications to the survey.

Recruitment

Subjects were purposefully selected. They were Swedish children presenting with a primary unilateral knee injury or a repeat injury. 8 sports clinics and a children's orthopedic clinic at a large medical center were involved. Purposeful sampling was used to address subject factors related to injury, reading skills (Blair and Srinath 2008), and factors related to sex and age. We selected an initial number of subjects in each age-sex category as a starting point. Eligibility criteria included: Swedish as the native language and naïve to KOOS (i.e. lack of familiarity with the KOOS through prior administration). 4 children were not eligible (2 were foreign-speaking and 2 had previously been exposed to the KOOS), leaving 34 in the sample. While no techniques are available to calculate sample sizes for qualitative study designs, sample sizes of 30 or more are common (Patton 1994, Sandelowski 1995). Children were sampled in blocks based on age and sex (10–12, 13–14, and 15–16) to obtain equal representation in six age/sex groups. One researcher (MÖ) reviewed the orthopedic clinic schedule on a monthly basis to identify children scheduled for a knee injury visit or physiotherapy clinic visit. Parents or guardians were contacted to obtain informed consent, following the institution's Human Subjects Review Board guidelines. Recruitment continued until saturation was reached, which occurred at 34 patients. Children and their caregivers were given 4 free movie tickets or a nominal fee ($43.00) for participating. The study was approved by Regional ethical board in Stockholm and was conducted according to the Declaration of Helsinki (2009-05-14, entry no. 2009/863-32).

Standardized training of interviewers

A behavioral scientist developed the interview protocols and verbal probes, in addition to providing structured training for a single interviewer using an established protocol (Iversen et al. 2010).

Interview protocol

The main researcher screened for the eligibility criteria. The interviewer explained the purpose of the study and obtained informed consent from the parent and child. The parents were instructed not to respond to the questions. The child was asked to read the KOOS directions aloud and restate the directions to each section in his or her own words. Before answering the survey, the child was instructed to read each question completely and to circle an item if he or she thought that it was too difficult. The interviewer observed and made notes while the child answered the survey, noting reactions to items. This information was then used to implement specific probes for the child. All interviews were recorded.

When the child had completed the form, the interviewer discussed the child's interpretation of the form, using general and scripted, tailored, verbal probes. These probes were used to solicit information regarding the processes used to answer each item. The interviewer probed for specific information relevant to the item, using both retrospective and concurrent probing technique (Willis et al. 1991, Tourangeau et al. 2002). Retrospective probing was emphasized more because it is more effective when assessing self-report questionnaires (Lessler and Sirken 1985, Willis et al. 1991, Jobe et al. 1993). A list of verbal probes for the interview process is included in Table 1 (see supplementary data). The interviewer also made verbal substitutes for items and phrases not understood by the children, to make survey modifications.

Interviews focused on 4 main areas: (1) item comprehension (language/jargon), (2) information retrieval and recall strategies (e.g. date of injury), (3) decision-making processes used to answer the item, and (4) the response process or how the child's answers aligned with the responses provided in the survey. The interviewer observed and probed the child for meaning and interpretation of items as well as noting the level of difficulty in selecting a response (Lessler and Sirken 1985, Presser and Blair 1994, Blair and Srinath 2008). A medical transcriptionist who was not present during the interviews transcribed the recordings.

Analysis

A team of 4 researchers analyzed the transcripts independently and subsequently met to identify themes and issues arising from the interviews using a normative group process. Analysis focused on problem detection, which included tab-

ulating counts of difficult survey items and suggestions for modifications, and theme identification to identify universal responses, reactions, and similarities in paraphrasing of items (Tourangeau 1984, Oksenberg et al. 1991, Maynard et al. 2002, Willis 2005). Quotes were extracted from interviews to illustrate comprehension issues and suggestions for revising items. The second phase required sorting of problematic issues into the following categories: comprehension/lexical (addressing the meaning of phrases or medical jargon), question/item format, response format, or mapping issues (ability to align question with response options) using data from all subject interviews regardless of age or sex. Themes were then analyzed by subgroup to determine whether specific issues were more common among specific ages, in one sex, or depending on surgery or physiotherapy treatment. This process of analyzing comprehension issues and response error led to specific modifications of the questionnaire (Oksenberg et al. 1991, Willis 2005, Iversen et al. 2010) Using the process described above, the KOOS was modified simultaneously in Swedish and English.

Results

We present interview results as general observations about the survey and survey instructions. Item-specific comments are illustrated by selecting key examples with the original question, children's comments, and the revised question in Table 2 (see supplementary data). Overall, 2,128 comments about the 42 items were generated. Comments were sorted into 4 major categories related to difficulty in understanding of and in responding to items; language comprehension (e.g. reading level/phrasing) and medical jargon; item format (content and time frame); response-set format; and response mapping. Table 3 is a summary of these issues by category and survey question.

General observations

Many children found the main and subheading instructions confusing from a lexical and formatting point of view, stating that it was easy to forget the question stem. For example, when asked to report on symptoms or function over a week, they were unsure whether "week" referred to a school week or 7 consecutive days. The general instructions were modified to: "These questions collect information about how your injured knee affects you. Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please select the best answer you can". Directions for individual subscales were removed.

Children did not understand the distinction between phrases such as "degree of pain" or "degree of difficulty", considering these equivalent constructs. As a result, they considered several items to be redundant (S4/P3, S5/P4, P2/SP4, P5/A6, P6/A1+2, P8/A14, P9/A4, and A3/A15; see supplementary data). The questionnaire format was modified to show the transition to a new construct. Children also thought that some items were irrelevant because they did not see how the activities could affect an injured knee (e.g. A8, A11, A13, A15, and A17). Participants also missed the transition in directions of items referring to "how often" symptoms occurred and "the amount of" symptoms or difficulty. 6 children had difficulty in selecting a response (mapping) if they had not performed the activity or were not allowed to perform it due to the risk of further injury. Children suggested adding a "not applicable" response for these items. Double-barreled items, defined as questions containing 2 or more constructs (S2, S3, S7, P6, P8, and A13), presented problems. The response option "moderate" was constantly perceived as confusing. While most children could interpret the meaning of the word due to its location in the middle of the response alternatives, they could not define the word and suggested replacing "moderate" with "some". This suggestion was implemented in the new questionnaire.

Finally, many children commented that the KOOS had obviously been developed for adults because the activities were not representative of children's daily activities. For example, children noted that there were no items referring to activities such as attending school, playing sports, and spending time with friends. Some children reported that the KOOS did not reflect the problems they experienced, due to the limited number of items dedicated to strenuous activities.

Comments on subscales

Item-specific comments are presented as key examples in Table 2 (see supplementary data).

Symptoms subscale *(S1–S7) (Appendix).* 16 children did not understand the word "symptoms" and suggested "knee problems" as a better way of describing the desired information. This change was made in the new questionnaire (Tables 4 and 5; see supplementary data). In addition, most did not carry over the concept of answering these items using the previous week as a time frame. Thus, the time frame was added to each item in the revision. *Item S1* (knee swelling): The children understood the concept of swelling but were uncertain how to select an answer if their swelling was constant. *Item S2* (knee grinding/clicking): 32 children had difficulty in understanding the terms "grinding" and "clicking", with the most predominant problems related to the term "grinding". *Item S3* (knee catching): 15 children had difficulty with the concepts of "catch" or "hang up". If they did understand the terms, they were confused about the concept on which to base their response. *Items S4 and S5* (knee flexion/extension): Some children confused the terms extension and flexion. Others reported that they did not know whether to answer the item based on their ability to perform the activity alone or with help (e.g. assisted by a physiotherapist). A few children wanted to know whether the item referred to difficulty in performing the action based on pain, e.g. "I thought it was pretty difficult, since I can stretch fully, but it hurts to stretch fully"

Table 3. Children's report of issues with completing the KOOS sorted and presented by item (n=34). Values are number reporting these issues

Original questions from KOOS	Comprehension / terminology	Item format	Response format	Mapping
Item S1 Do you have swelling in your knee?	0	29	1	1
Item S2 Do you feel grinding, hear clicking or any other type of noise when your knee moves?	33	22	1	2
Item S3 Does your knee catch or hang up when moving?	15	20	0	1
Item S4 Can you straighten your knee fully?	2	20	1	1
Item S5 Can you bend your knee fully?	3	21	0	2
Item S6 How severe is your knee joint stiffness after first wakening in the morning?	7	20	9	2
Item S7 How severe is your knee joint stiffness after sitting, lying or resting later in the day?	11	23	9	0
Item P1 How often do you experience knee pain?	5	9	9	6
Item P2 Twisting/pivoting on your knee	22	10	12	3
Item P3 Straightening knee fully	16	9	11	1
Item P4 Bending knee fully	4	9	9	3
Item P5 Walking on flat surface	4	9	11	0
Item P6 Going up or down stairs	4	17	9	6
Item P7 At night while in bed	3	9	10	0
Item P8 Sitting or lying	6	11	9	0
Item P9 Standing upright	8	9	9	1
Item A1 Descending stairs	14	8	9	0
Item A2 Ascending stairs	4	8	9	4
Item A3 Rising from sitting	9	8	10	0
Item A4 Standing	14	9	8	1
Item A5 Bending to floor/pick up an object	16	8	11	1
Item A6 Walking on flat surface	10	8	10	1
Item A7 Getting in/out of car	6	8	9	0
Item A8 Going shopping	25	9	9	1
Item A9 Putting on socks/stockings	5	8	8	0
Item A10 Rising from bed	6	8	7	0
Item A11 Taking of socks/stockings	1	8	9	0
Item A12 Lying in bed (turning over, maintaining knee position)	12	8	9	1
Item A13 Getting in/out of bath	5	23	10	1
Item A14 Sitting	13	8	9	1
Item A15 Getting on/off toilet	7	7	7	1
Item A16 Heavy domestic duties (moving heavy boxes, scrubbing floors etc)	5	8	9	4
Item A17 Light domestic duties (cooking, dusting etc)	7	8	9	1
Item SP1 Squatting	10	8	8	5
Item SP2 Running	15	10	9	5
Item SP3 Jumping	9	9	7	5
Item SP4 Twisting/pivoting on your injured knee	23	8	8	4
Item SP5 Kneeling	31	8	7	2
Item Q1 How often are you aware of your knee problem?	15	1	5	1
Item Q2 Have you modified your life style to avoid potentially damaging activities to your knee?	8	1	8	1
Item Q3 How much are you troubled with lack of confidence in your knee?	13	1	9	1
Item Q4 In general, how much difficulty do you have with your knee?	19	2	2	3

Directions on stiffness. Overall, children did not understand the phrase "joint stiffness" though many understood stiffness as a concept. *Items S6 and S7* (joint stiffness): 27 children reported problems with these items. Specifically, questions arose from use of "joint stiffness" in S7 and with the inclusion of many different body positions. While the intent with the item is to determine whether stiffness occurs after prolonged or brief inactivity, the children focused on stiffness with body position. Many children stated that they never took afternoon naps, so the question was irrelevant. Children overlooked the fact that the items asked about "amount of" stiffness and answered based on "how often" they experienced joint stiffness. Also, 9 children specifically reported that they did not understand the term "moderate" and wished to replace the responses with "a little" instead of "mild" and "some" instead of "moderate". These suggestions were implemented.

Pain subscale (P1–P9). The first question refers to frequency of pain over a number of days up to a month. Many children were confused by the responses, since the time frame shifted to a longer duration. Also, a few children noted that if you have pain daily then you also have pain over a week or a month. In the revised KOOS, the monthly time frame was kept; however, the response set was changed to make the item more easily understood. *Items P2–P9* (amount of pain with various activities): 12 children answered several items based on difficulty with the movements as opposed to the amount of pain. Again, children had trouble with the phrase "moderate". 22 children reported difficulties with the concept "twisting and pivoting" in *item P2*. Their perception of this motion was quite different from the item's intent, as illustrated by the

following quotes, "Is it when you sit on your knees and turn, or?", "You kind of sit with your legs crossed and maybe you try to spin a little?". Some children wondered whether the item referred to both knees or only to the injured knee. More than a quarter of the children felt *P3* and *P4* (full knee flexion and extension) were duplicated in the symptoms subscale (*S4* and *S5*), because they focused on ability to complete the movement rather than on pain with movement. With respect to walking "on a flat surface" (*P5*), comments arose about the intent of the phrase and 24 children suggested replacing this phrase with "floor" or "asphalt". *Item P6* referred to pain on climbing and walking down stairs. As pain differed with these 2 activities, children were unsure of how to respond (e.g. "I get more pain when I walk downstairs and less pain when I walk upstairs"). In *Item P8,* body position influenced how the child responded. For example, "I chose 'none' because when I lie down it's OK. Sitting depends on how you sit—whether you sit on your knees or sit normally".

ADL subscale (A1–A17). These items refer to difficulties with everyday functional activities. More than half of the children (n = 18) missed the shift in focus from pain to difficulties with activities. 7 children believed that pain and difficulty were similar and considered these items redundant. Children felt the responses to *Items A3* and *A4* depended on the sitting or standing position and on the length of time in these positions (e.g. "It depends on how long I've been sitting and where I have sat, like, if I've been sitting on the floor it's harder to get up". 12 children stated that the answer to item *A5* (degree of difficulty when bending to floor/picking up an object) would depend on whether you bend at the back or knees, and 2 children felt that it would be silly to bend the knee (e.g. "If I were to bend forward with just the upper body, it doesn't hurt but if I were to squat—which I definitely wouldn't do because it makes it worse for my knees—then it would really hurt"). Children reported that *Items A7* (bathing) and *A13* (showering) were not related to a knee injury. Additional items that children felt were irrelevant were items *A8, A15, A16,* and *A17*—all of which asked about daily adult activities such as shopping and cleaning. *Item A8* generated a great deal of comments, e.g. with respect to shopping: "it's more that you're picking things from the shelves, and I have no problem with my arms", "I have never gone shopping...what should I fill in then?". *Items 16* and *17* are items related to cooking and cleaning, activities not usually performed by these children (e.g. "I do not know what scrubbing a floor is", "I have never tried this, doing heavy housework. I guess it's not very difficult; it's mostly arms and stuff so I go with 'none'"). 4 Children did not find *A10,* "rising from bed", important because they thought it was similar to *A3* which asks about "rising from sitting". *Item A12,* turning in bed, presented a conceptual dilemma as children viewed turning over while in bed and maintaining knee position in bed as opposing concepts. 10 children felt that the answer to *Item A14* depended on the sitting position and on the time spent sitting.

Sports and recreational (SP1–SP5). When children were told not to perform an activity, (e.g. items *SP3, SP4,* and *SP2*), they were unsure of how to answer the questions. They suggested adding a "not applicable" box. 6 children did not understand the phrase "squatting" (*SP1*). Some thought it meant squatting to the floor and others felt it referred to sitting on your knees. For *Item SP3,* 8 children felt their answer to jumping would depend on how they jump. 15 children thought that there were no differences between *Item SP4* and *Item P2,* missing the references to difficulty or pain. 29 children had difficulty in understanding *Item SP5,* which refers to kneeling. Conceptually, kneeling was described as "lying down on your belly with knees to the floor" or "bending your knees backwards and lying on your back"). Some requested pictures to help illustrate the action. This change has been implemented.

Quality of life (Q1–Q5). Some children suggested that quality of life meant "How you, like, feel in life—not mentally but physically"). The concept was changed in the revised KOOS to "how has your knee injury affected your life?". *Item Q1* was difficult for 7 children to understand, as they found the response alternatives confusing (e.g. "I don't like the choices 'every month' and 'every week'. If there is pain every week, it's also occurring every month…"). *Item Q3* asks about trust or confidence in their knee. Children did not understand what was meant by 'to what extent' they trusted their knee, and they could not select a response. For example, 2 children noted, "how much can you extend your knee…?" and "if I could trust that I would have been able to stretch it". They preferred to rephrase the item as follows: "How much do you trust your knee?". This suggestion was implemented. With Item *Q4,* 18 children had trouble with the phrase "difficulties in general" with the knee. Some children felt that this referred to a pre-injury state (e.g. "Generally means, like, as in ordinary cases, so before the injury I had, like, no problems". The children suggested replacing the word with "overall". This suggestion was implemented.

Observations regarding differences in completing and comprehending the KOOS form based on age, sex, physiotherapy treatment, and surgery

Children of different ages raised different concerns with the survey. In 14 of the 21 items, the youngest children reported having more difficulties with item comprehension than the 2 older groups. In items P3, P5, P7, A6, A7, and Q1–4, the youngest age group raised more issues than the other 2 older groups, and in S4, P4, P9, A9, and A17 the youngest children had more difficulties than the oldest children.

There were no sex differences regarding comprehension of KOOS items, except for item P1 where boys had more comments than girls (71% vs. 47%). However, in 13 items (S5, P3, P5–7, P9, A1, A2, A5–7, A9, and SP1), there was a difference in interpretation of items between those who had received physiotherapy and those who had not. The children who had been treated by a physiotherapist had fewer com-

ments then the untreated group. The same phenomenon was found between children who had had knee surgery and those in the non-surgery group.

Discussion

Children raised many concerns regarding comprehension of items, directions, time intervals, and use of medical terms/jargon. The present findings illustrate that the use of the original KOOS may not be appropriate for children, particularly children in the 10- to 12-year age group. This being so, modifications are needed to improve its comprehensibility and validity for use with children. Based on our results, we modified the KOOS in the following areas: general instructions, lexical/language (terminology and grammar), item format, response format, and mapping. We also believe that some changes in layout will better illustrate transitions between items asking about pain or difficulty. The pediatric version of the KOOS was modified in Swedish and English, matching the original language versions of the KOOS.

Cognitive interviewing allows the researcher to gain insight into potential problems that may arise with a questionnaire. While this process is time-consuming, it has been shown that children can handle the reading and respond to probes as they complete a questionnaire (Drennan 2003). Cognitive interviewing has been effective for pretesting questionnaires in children (Iversen et al. 2010). In the present study, a few children chose to think aloud while completing the questionnaire, while others responded to concurrent or retrospective probes. Our results illustrate that modification of questionnaires for use in children is indicated and that cognitive interviewing is an appropriate methodology for identification of areas of concern and of recommendations for improvement. To our knowledge, no valid or reliable knee-specific patient-reported outcome measure for children is currently available in Swedish. However, a recent study by Iversen et al. (2010) evaluated the IKDC in children using the same methodology. The authors modified and developed a Pedi-IKDC version that has been shown to have good validity and reliability when tested in a large population of American children aged 10–18 years (Iversen et al. 2010, Kocher et al. 2010).

In accordance with the findings of Iversen et al. (2010) when evaluating the IKDC in children, children perceived the directions for the KOOS to be cumbersome and unclear—for example, missed nuances regarding certain items, uncertainty regarding which knee certain items were referring to, time frame and lexical issues, and reference to items that were not relevant to the children's lifestyle.

As in our investigation, the issue of double-barreled items was a major source of difficulty found in the IKDC. These items were therefore revised in the new child-friendly version of the KOOS, keeping constructs separate. The comprehension problems associated with double-barreled questions have been illustrated by Oksenberg et al. (1991). The use of a single construct for each question reduces misunderstanding and response-mapping issues (Tourangeau 1984, Tourangeau et al. 2002).

Difficult terms and medical jargon often lead to misunderstandings, confusion, and missed or default responses (Willis et al. 1991, 1999). In this study, we used the children's suggestions for modification of items. We added pictures to the sports and recreational section, since there were numerous misunderstandings about the terminology. With respect to the response sets, the children appeared to understand the 5-point Likert response-set format. However, many children had difficulties with the word "moderate", as also noted previously (Iversen et al. 2010). We modified the wording of questions and response sets using the children's suggestions, e.g. "some" instead of "moderate" to reduce the risk of misunderstandings and mapping issues.

The children suggested including a "not applicable" alternative, especially for the items relating to sport and recreation function—since at times they were not allowed to perform these items. This suggestion was not implemented for 2 reasons: first, the items should be answered with regard to perceived difficulty and not if the activity is performed or not; secondly, including a "not applicable" box would preclude determining a change over time. Instead, the subjects are asked to score "extreme" if not allowed to perform the activity. If the patient does not usually perform the activity, then they are instructed to leave the item blank. Futher information is available in the KOOS-Child users guide, www.koos.nu.

Many children believed that their main problems were not investigated fully with the KOOS. For example, some children reported they had mild problems throughout the survey until they answered the last item, "Have you modified your lifestyle to avoid potentially damaging activities to your knee?" and then answered "totally". When probed, the children felt that activities included in the KOOS did not correspond to what they did on a daily basis. Questions were added about maintaining balance, participating in sports, school activities, and social participation. The psychometric properties of these new items will be fully investigated in a future study of the KOOS-Child survey. Since many children are active individuals, either in play and/or in sports, complementing the KOOS-Child with an activity scale may be advantageous. It is important that an activity rating scale is used as a secondary outcome measure following orthopedic surgery. However, activity scales should not be used for comparisons between groups but can be used to measure individual changeover time (Roos et al. 2011).

At this time, all the original KOOS content remains but most of it has been revised. We are also evaluating the changes in the survey with psychometric testing. The study has many strengths. The children were selected from a large orthopedic unit located in a tertiary medical center and from different physiotherapy clinics, to obtain a broad representation of children with knee injuries. We purposefully selected children to

allow equal group representation of age and sex. We selected an initial number of subjects as a starting point and then continued until saturation was reached, which gave a relatively large sample size for this qualitative study. While there is no gold standard for calculation of sample sizes for qualitative studies, subject factors, number of items, and application of the questionnaire are important considerations (Sirken et al. 1999,Willis 2005, Blair and Srinath 2008). We considered these factors in the design of our sampling strategy and continued recruitment until saturation was reached.

Children who had undergone surgery or physiotherapy appeared to have fewer problems in understanding the KOOS. However, children with less exposure to medical terminology had greater problems in understanding the KOOS. Thus purposeful sampling allowed us to explore these differences and to provide recommendations that would be useful for a broader group of children.

The number of instruments for measurement of patient-relevant outcomes is increasing, and today there are a substantial number of different self-administered instruments for measuring knee outcomes in adults. However, the target population and the specific knee problem must be considered, since there is no standardized form for all groups of patients or knee diagnoses (Wang et al. 2010). Self-reported questionnaires rely on lexical comprehension, and this is especially important to consider when they are used in a young population (Iversen et al. 2010). Today, in the clinic, questionnaires designed for adults are often used for children due to a lack of suitable, validated instruments for this population. Thus, the potential exists for inaccurate evaluation and selection of treatments for children.

This study has shown that the original KOOS is not appropriate for use in its original form in younger children (aged 10–12 years) and needs to be modified for this purpose. The current study was not designed to determine a definite age cut-off for the use of the KOOS, rather the intent was to develop a version appropriate for use in children. Determination of a definite age cut-off should be the subject to future research. Our future research will also concentrate on evaluating the psychometric properties (reliability, validity, and responsiveness) of the new KOOS-Child questionnaire.

Supplementary data

Tables 1, 2, 4, and 5 are available at our website (www.actaorthop.org), identification number 5292.

MÖ, ER, EB, and MDI participated in the design of the study. MI developed the interview items and interview protocol, and trained MÖ. MÖ and PMJ participated in coordination and recruitment of the individuals included in the study. MÖ, EB, PMJ, and MDI carried out the analyses of the cognitive interviews and all authors participated in modification of the KOOS-Child. MÖ, MDI, and ER drafted the manuscript. All the authors then reviewed, commented on, and approved the final manuscript.

Funding was provided by Stiftelsen Promobilia, Karolinska Institutet, and Trygg-Hansa. We thank the physiotherapy clinics (Sport och Rehabkliniken Vasastan, Sergelkliniken Stockholm, Ekerö Fysio Center, Idrottskliniken Stockholm, Fältöverstens sjukgymnastik, Sportskadekliniken Stockholm, OS-kliniken, and Bosön) for their help with recruiting patients to this study, and we also thank Mathias Karlsson for drawing the illustrations in the KOOS-Child.

No competing interests declared.

Blair J, Srinath K P. A note on sample size for behavior coding pretest. Field methods 2008; (20): 85-95.

Drennan J. Cognitive interviewing: verbal data in the design and pretesting of questionnaires. J Adv Nurs 2003; (42): 57-63.

Garratt A M, Brealey S, Gillespie W J. Patient-assessed health instruments for the knee: a structured review. Rheumatology (Oxford) 2004; (43): 1414-23.

Irrgang J J, Anderson A F, Boland A L, Harner C D, Kurosaka M, Neyret P, Richmond J C, Shelborne K D. Development and validation of the international knee documentation committee subjective knee form. Am J Sports Med 2001; (29): 600-13.

Iversen M D, Lee B, Connell P, Andersen J, Anderson A F, Kocher M S. Validity and comprehensibility of the International Knee Documentation Committee Subjective Knee Evaluation form in Children. Scand J Med Sci Sports 2010; 20: e87-e95.

Jobe J, Tourangeau R, Smith A. Contributions of survey research to the understanding of memory. Applied cognitive Psychology 1993; (7): 567-84.

Kocher M S, Smith J T, Iversen M D, Brustowicz K, Ogunwole O, Andersen J, Yoo W J, McFeely E D, Anderson A F, Zurakowski D. Reliability, Validity, and Responsiveness of a Modified International Knee Documentation Committee Subjective Knee Form (Pedi-IKDC) in Children With Knee Disorders. Am J Sports Med 2010; 5: 933-9.

Lessler J T, Sirken M G. Laboratory-based research on the cognitive aspects of survey methodology: The goals and methods of the national center of health statistics study. Milbank Memorial Fund Quarterly/ Health and Society 1985; 63: 565-81.

Lysholm J, Gillquist J. Evaluation of knee ligament surgery results with special emphasis on use of a scoring scale. Am J Sports Med 1982; 10: 150-4.

Maynard D W, Houtkoop-Steenstra H, Schaeffer N C, van der Zouwen J. Standardization and tacit knowledge: Interaction and practice in the survey interview. John Wiley & Sons, New York 2002.

Oksenberg L, Canell C, Kalton G. New strategies for pretesting survey questions. J Official Stat 1991; 7: 349-65.

Patton M Q. Qualitative evaluation and research methods. Sage, Newbury Park 1994.

Presser S, Blair J. Survey pretesting: Do different methods produce different results? Soc Method 1994; 24: 73-104.

Roos E M, Toksvig-Larsen S. Knee injury and Osteoarthritis Outcome Score (KOOS) —validation and comparison to the WOMAC in total knee replacement. Health Qual Life Outcomes 2003; 1: 17.

Roos E M, Roos H P, Ekdahl C, Lohmander L S. Knee injury and Osteoarthritis Outcome Score (KOOS)—validation of a Swedish version. Scand J Med Sci Sports 1998a; (8): 439-48.

Roos E M, Roos H P, Lohmander L S, Ekdahl C, Beynnon B D. Knee Injury and Osteoarthritis Outcome Score (KOOS)—development of a self-administered outcome measure. J Orthop Sports Phys Ther 1998b; 28: 88-96.

Roos E M, Engelhart L, Ranstam J, Anderson A F, Irrgang J J, Marx R G, Tegner Y, Davis A M. ICRS Recommendation document: Patient-reported outcome instruments for use in patients with articular cartilage defects. Cartilage 2011; 2: 153-72.

Sandelowski M. Sample size in qualitative research. Res Nurs Health 1995; 18: 179-83.

Sirken M, Herrmann D, Schechter S, Schwarz N, Tanur J, Tourangeau R. Cognition and survey research. Wiley, New York 1999.

Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. Clin Orthop 1985; (198): 43-9.

Tourangeau R. Cognitive sciences and survey methods. In: Cognitive Aspects of Survey Methodology: Building a Bridge Between Disciplines. (Eds. Jabine T, Straf M, Tanur J, Tourangeau R). Washington DC: National Academy Press, 1984; 73-100.

Tourangeau R, Rips L J, Rasinski K. The psychology of survey response. Cambridge University Press, Cambridge 2002.

Wang D, Jones M H, Khair M M, Miniaci A. Patient-reported outcome measures for the knee. J Knee Surg 2010; 23: 137-51.

Willis G B. Cognitive interviewing: A tool for improving questionnaire design. Sage Publications, Thousand Oaks 2005.

Willis G B, Royston P, Bercini D. The use of verbal report methods in the development and testing of survey questionnaires. Applied cognitive Psychology 1991; 5: 251-67.

Willis G B, DeMaio T J, Harris-Kojetin B. Is the bandwagon headed to the methodological promised land? Evaluation of the validity of cognitive interviewing techniques. In: Cognition and Survey Research. (Eds.Sirken M, Herrmann D, Schechter S, Schwarz N, Tanur J, Tourangeau R). New York: Wiley, 1999.