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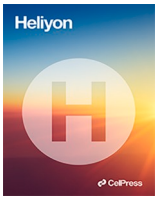

Research article

Development and assessment of a knowledge, attitude, and practice (KAP) questionnaire for genetic counselees with preimplantation genetic testing (PGT) indications

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ABSTRACT

Background: Preimplantation genetic testing (PGT) can reduce the risk of familial genetic diseases, chromosome abnormalities, and recurrent abortions. It is unclear whether genetic counselees with PGT indications understand and accept the implications of PGT. A well-developed and validated tool is needed to evaluate the knowledge, attitude, and practice (KAP) levels of genetic counselees with PGT indications. The purpose of this study was to develop and validate a PGT KAP questionnaire (PGT-KAP-Q) for genetic counselees with PGT indications.

Methods: First, we established an item pool based on a literature review and qualitative interviews. Second, we developed the PGT-KAP-Q using the Delphi method. Third, we evaluated the quality of the questionnaire using item analysis and psychometric evaluation. The item analysis included extreme value comparison, application of the correlation and Cronbach's alpha (α) coefficient methods, and factor analysis. We also evaluated the content and structural validity of the questionnaire, as well as the internal consistency, test–retest reliability, and split-half reliability.

Findings: After the literature review and interviews, and based on three rounds of expert consultations, we formed a 43-item questionnaire. In the validity analysis, the item's content validity index (I-CVI) and the average scale level CVI (S-CVI/Ave) values (>0.78 and >0.95, respectively) confirmed the questionnaire's content validity. Exploratory factor analysis showed that all 43 items had strong factor loadings (>0.4), and the three factors of the PGT-KAP-Q explained 51.97 % of the total variance. The Cronbach's α coefficient for the questionnaire was 0.95 ($p < 0.05$), the split-half reliability was 0.76 ($p < 0.05$) and the test–retest reliability coefficient was 0.78 ($p < 0.05$).

Interpretation: The 43-item PGT-KAP-Q for genetic counselees with PGT indications is reliable and valid. It contains a moderate number of items, is easy for patients to understand and accept, and can be used for clinical research and applications.

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1. Introduction

Preimplantation genetic testing (PGT) is widely used in in-vitro fertilization (IVF) centers around the world to select euploid embryos for embryo-transfer and to improve the clinical outcomes of embryo implantations, clinical pregnancies, and live birth rates [1]. PGT can screen out embryos with serious genetic diseases or chromosomal abnormalities, allowing embryos with normal genetics to be selected for transplantation and thus reduce the risk of familial genetic diseases and/or recurrent abortions [2]. As a reproductive intervention technology, PGT not only effectively prevents next-generation birth defects and genetic diseases, but can also reduce the physical and psychological damage caused by pregnancy terminations due to positive prenatal diagnosis [3,4]. Due to the development of sequencing technology, PGT is now widely used to support assisted reproductive technology (ART). More than 7600 babies in over 50 countries have been born from PGT [5].

To standardize PGT technology and make it more effective, *an expert consensus on preimplantation genetic diagnosis and screening technology* was published at *Chinese Journal of Medical Genetics* in 2018 [6] to clarify PGT indications(Table 1). Pre-PGT couples are advised to receive genetic counseling at least once. This enables them to make reproductive decisions based on counseling records and a full understanding of their own fertility and genetic risks, as well as possible medical interventions and their advantages and disadvantages [6]. During this process, couples should be made aware of feasible reproductive choices (such as prenatal PGT, gamete donation, etc.), the advantages and disadvantages of different interventions, and the risks of the ART treatment cycle with PGT. These risks may include the IVF process, the outcomes of embryo biopsy, cryo-resuscitation injuries, possible undetected abnormalities of individual embryos, a lack of transplantable embryos, the uncertainty of chromosomal chimeric embryo development, failure to routinely identify abnormal chromosome carriers, misdiagnosis due to the biological characteristics of embryos, and the limitations of testing technology [6].

The rapid development of PGT has increased genetic counselees' understanding of PGT indications, facilitating effective reproductive choices [7]. However, in China, understanding and acceptance of PGT may vary widely [8,9]. The development of PGT technology is relatively new, the professional content that needs to be discussed in genetic counseling is complex, and counseling sessions may be too short for counselees to thoroughly understand the implications. These difficulties may affect counselees' acceptance of PGT [9,10].

The knowledge, attitude, and practice (KAP) model aims to change human behavior and generate positive and healthy beliefs based on relevant knowledge of healthy behaviors [11]. However, few studies have examined the KAP levels of genetic counselees with PGT indications. Moreover, they have mainly considered the current situation based on qualitative interviews with genetic counselees about PGT KAP. The existing research has mainly considered self-created KAP questionnaires without disclosing the reliability and validity results of the tools. Only two studies provided Cronbach's α coefficient values for the knowledge questions in their questionnaires [7,12].

The aim of this research was to develop a tool for assessing the PGT KAP levels of genetic counselees with PGT indications and to provide a sound basis for proposing targeted interventions. We developed a PGT KAP questionnaire (PGT-KAP-Q) for genetic counselees with PGT indications and evaluated its reliability and validity.

2. Methods

2.1. Design

Based on the KAP theoretical framework, we conducted a multi-phase questionnaire development method, which was divided into three parts: 1) item generation based on a literature review and interviews, 2) development of the PGT-KAP-Q using the Delphi technique, and 3) item analysis and psychometric evaluation to validate the PGT-KAP-Q. This study was conducted at the Reproductive and Genetic Hospital of CITIC-Xiangya between August 1, 2021, and January 31, 2022 (Fig. 1).

Phase I Item generation

Table 1
PGT indications.

Classification	Indications
Preimplantation genetic testing-structural rearrangements (PGT-SR)	Chromosome abnormality (e.g. translocations, inversions, deletions, and insertions)
Preimplantation genetic testing-monogenic (PGT-M)	Monogenic disease, serious disease with a genetic predisposition, human leukocyte antigen-compatible
Preimplantation genetic testing-aneuploidy (PGT-A)	Advanced maternal age, recurrent miscarriage, recurrent implantation, severe teratozoospermia

2.2. Literature review

We conducted a thorough literature review to identify existing questionnaires relating to the KAP of genetic counselees with PGT indications. The search was limited to 1) studies published up to May 31, 2021; 2) primary studies that examined PGT KAP; 3) studies with available abstracts; and 4) articles written in English or Chinese and held in electronic databases. The exclusion criteria were clinical guidelines or recommendations, editorials, and reports of expert opinions. The databases included PubMed, Web of Science, MEDLINE (OvidSP), EMBASE, CINAHL, CNKI (Chinese), and WANGFANG DATA (Chinese). We used Endnote 20 to remove duplicate studies, and we thoroughly screened the titles and abstracts based on the review's inclusion and exclusion criteria. We manually examined the reference lists of the remaining articles to identify additional relevant studies and contacted the authors when full-text articles were unavailable.

2.3. Individual interviews

To explore baseline knowledge and views regarding PGT and to generate appropriate items, we conducted semi-structured individual interviews with genetic counselees who had PGT indications. Questions included, "Do you know what preimplantation genetic testing (PGT) is?," "What do you think are the advantages and disadvantages of PGT?," "Are you worried about PGT," and "Do you learn from or communicate with others about PGT?" We continued sampling until we achieved saturation of the themes [13]. The interviews were transcribed and analyzed using Colaizzi's data analysis method, which included: 1) reading the interview materials, 2) extracting significant statements, 3) formulating meanings for each significant statement, 4) organizing created meanings into thematic clusters, 5) creating exhaustive descriptions of the themes, 6) producing an essential structure, and 7) discussing the findings with the interviewees to confirm and modify the findings [14].

Phase II Item screening

2.4. Delphi technique

We developed the first draft of the PGT-KAP-Q in Chinese after completing Phase I and evaluated it using the Delphi technique with invited experts in genetics, reproduction, ethics, and nursing who each had more than 10 years of clinical experience in China. According to the study's purpose, complexity, and resources, we determined 10–15 experts to be appropriate for inclusion [15]. These experts were also invited to identify and judge the content validity in Phase III.

We designed a questionnaire to assess correspondences among the experts' opinions, which included a preface, a consultation table, and general information questions for the experts. We scored all items in the consultation table using a five-point Likert scale (1 = not important, 2 = slightly important, 3 = moderately important, 4 = very important, 5 = extremely important). We also asked the experts

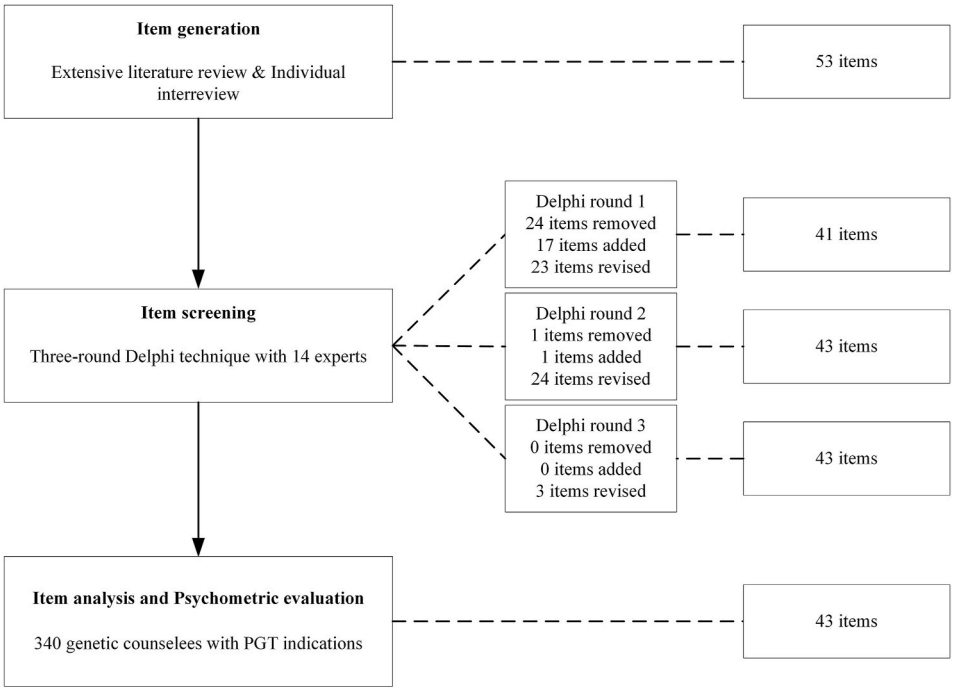

Fig. 1. Flowchart of the study.

to comment on the overall format, domains, rating method, and items of the draft PGT-KAP-Q. We also collected data on the experts' ages, genders, educational levels, work experience, specialties, and job titles.

We conducted the Delphi technique in September–November 2021 and asked the experts to complete and return the questionnaires within a week. In each round of expert evaluation, we analyzed and discussed the correspondences, data, and experts' opinions item by item. Since the experts' opinions tended to be consistent, and there was no further need to add, delete, or modify items, the Delphi process ended after three rounds of expert evaluation.

To evaluate the reliability of the correspondences among experts' opinions, we tested their positive coefficients, coordination level, authority coefficients, and convergence.

We used positive coefficients to reflect the degree of experts' enthusiasm for the research, as reflected by the response rate to the questionnaire. We considered a response rate >50 % appropriate for the data analysis, and >70 % indicated a highly positive response from the experts [16].

We used the level of coordination of experts' opinions to reflect the consistency of their opinions, as indicated by the coefficient of variation (CV) and coordination coefficient (Kendall's *W*) values. The smaller the CV (ideally less than 0.25), the higher the level of expert coordination [16]. The greater the statistical significance of Kendall's *W* ($p < 0.05$), the better the coordination level of experts' opinions [16].

We evaluated the experts' authority coefficients according to the basis of the judgmental and the degree of familiarity [16]. We considered an authority coefficient ≥0.7 acceptable, indicating the higher experts' credibility [17].

The convergence of the experts' opinions reflected the importance of the items as expressed by the average value for importance (sum of item importance scores/number of evaluation experts), acceptance rate (number of experts who assigned 4 or 5 points for the item evaluation/number of evaluation experts), and full-score rate (number of experts who assigned full scores for the item evaluation/number of evaluation experts). We generally found that, for each item, the average importance was >3.5, the acceptance rate was >80 %, and the full-score rate was >50 %, indicating an important item [18].

In this study, the revision principle for the items was that the screening indicators for the items should be 2 or more, and items should be added, deleted, or modified based on the experts' opinions and group discussion [19]. The screening indicators for the items included the following: 1) an average value of importance >3.5, 2) a CV of 0.25, 3) an acceptance rate >80 %, and 4) a full-score rate >50 %.

Phase III Item analysis and psychometric evaluation of the PGT-KAP-Q

2.5. Psychometric testing

2.5.1. Study setting and sampling

To evaluate the quality and establish a final form of the questionnaire, we distributed the questionnaire to genetic counselees with PGT indications who attended the Reproductive and Genetic Hospital of CITIC-Xiangya. We determined the sample size based on the recommended 5–10 participants per item for the factor analysis, accounting for a 20 % dropout rate [20]. We recruited a convenience sample of 320 genetic counselees with PGT indications, and the inclusion criteria included: 1) genetic counselees with PGT indications according to the *Expert consensus on preimplantation genetic diagnosis and screening technology* [6], 2) counselees with good cognitive and independent decision-making ability, and 3) voluntary participation, cooperation, and informed consent. There were no exclusion criteria other than the language requirements sufficient to understand the information and consent sheets provided [21].

The questionnaire consisted of five sections, three of which encompassed items pertaining to KAP, as well as sociodemographic items. The questionnaire was designed as a self-administered questionnaire according to standard questionnaire development guidelines and methodologies [22]. We used a three-point Likert scale for the knowledge dimension (2 = good understanding, 1 = a little but not accurate understanding, 0 = no understanding); a five-point Likert scale for the attitude dimension (4 = strongly agree, 3 = agree, 2 = no comment, 1 = disagree, 0 = strongly disagree); and a five-point Likert scale for the practice dimension (4 = always, 3 = often, 2 = sometimes, 1 = occasionally, 0 = never).

As mentioned, we employed a convenience sampling method. After obtaining the consent of the subjects, they were asked to voluntarily complete the PGT-KAP-Q, which was administered as an electronic form. Participants were asked to scan the QR code for the Wenjuanxing platform (www.wjx.cn) to access the questionnaire.

2.5.2. Item analysis

We used item analysis to assess the appropriateness/reliability of the items, and we deleted items when two or more of the following four analysis methods implied that the item was unsatisfactory [19].

1) Extreme value comparison: The decision value (CR) was used to evaluate the difference between the 27 % highest-scoring group and the 27 % lowest-scoring group based on the independent *t*-test method. If the CR value for each item was <3 ($p > 0.05$), it indicated that the item was poorly differentiated [23].
2) The correlation coefficients were evaluated using the Pearson correlation coefficient to measure the association between two variables according to the magnitude of the absolute value. If the Pearson correlation item-total value was <0.3 ($p > 0.05$), it indicated that the item was not representative [24]; if the Pearson correlation between each item and its relevant dimension total was <0.4 ($p > 0.05$), it indicated that the item was not representative [25]. If the Pearson correlation between each item and another dimension total was >0.4 ($p > 0.05$), it indicated that the item had poor independence [25].

3) The Cronbach's alpha (α) coefficient method was used to screen the internal consistency of the questionnaire. First, we calculated the questionnaire Cronbach's α, and then we recalculated the Cronbach's α after deleting each item. We compared the changes after removing an item if the Cronbach's α coefficient increased after removing the item, indicating that this item would reduce the internal consistency of the questionnaire [26].
4) Factor analysis was used to screen the representativeness of the items. Communalities refer to the variation of items explaining common traits or attributes: the higher the communalities, the higher the degree to which this factor can be measured, and the higher the homogeneity. Factor loading indicates the degree of relationship between items and factors; the higher the factor loading, the closer the relationship with factors, and the higher the homogeneity. If the communalities value was <0.20, or the factor loading for each item on its corresponding common factor was <0.45, it indicated no close relationship between the item and the factor [27,28].

2.5.3. Validity analysis

We assessed content validity by calculating each item's content validity index (I-CVI) and the average scale level CVI (S-CVI/Ave). Experts assessed the elements of the scales based on a Likert 4-item evaluation Table (1 = irrelevant, 2 = weakly relevant, 3 = strongly relevant, and 4 = extremely relevant) that measured the relevance of the items. Responses of 3 and 4 were recorded as 1, representing relevance, and responses of 1 and 2 were recoded as 0, representing irrelevance. To ensure the accuracy of the content validity results, the number of experts should generally be 3–10, [29] and an $I\text{-}CVI \geq 0.78$ and an $S\text{-}CVI/Ave \geq 0.90$ suggest good content validity [23]. To evaluate the chance agreement degree of experts' appraisals and ratings for each item, we calculated the Kappa value (K^*) [23]. Generally, a K^* value of 0.40–0.59 is average, a value of 0.60–0.74 is good, and a value greater than 0.74 is excellent [23,30]. The higher the K^* value, the greater the I-CVI, and the higher the consistency of expert opinions [30].

We assessed the construct validity of the questionnaire using exploratory factor analysis (EFA). We employed the varimax rotation method to identify correlations between items and construct the factors, and we used the Kaiser–Meyer–Olkin (KMO) test to determine sample adequacy. A KMO value close to 1 indicated the sample efficiency and its appropriateness for factor analysis. A KMO >0.9 is highly suitable for factor analysis, and a KMO >0.7 is still moderately suitable. We conducted a Bartlett's test of sphericity and considered a p value < 0.05 acceptable. We employed principal component analysis to estimate the factor loadings [31]. If the cumulative contribution rate of the extracted common factor exceeded 50 %, and the factor loading for each item on its corresponding common factor was more than 0.4, it was considered to have good structural validity [27].

2.5.4. Reliability analysis

We assessed the internal consistency using Cronbach's α coefficient, which was expected to be higher than 0.7 [23]. Higher than 0.9 indicated excellent internal consistency [32]. We measured the test–retest reliability using the Pearson correlation coefficient between two time-points with a gap of 2 weeks for 40 randomly selected participants. The test–retest reliability for each dimension was >0.7 ($p < 0.05$), indicating that the test–retest reliability of the questionnaire was good [33]. We assessed the split-half reliability using Spearman–Brown correction. A value > 0.7 indicated good homogeneity [23].

2.6. Data analysis

We collected data from the experts and survey participants using the Wenjuanxing platform (www.wjx.cn), and then extracted and analyzed the data using IBM® SPSS® 26.0 software.

Ethical approval

This study was approved by the ethics committee of the Reproductive and Genetic Hospital of CITIC-Xiangya (LL–SC–2022-003) on July 30, 2021, which followed the principle of voluntary participation. Participants were informed about the research purpose, content, and significance before data collection started. Consent was implied with completion of the anonymous survey. Participants could withdraw at any time without risking the loss of rights and interests. The collected data were only used for this research, and no personal information was requested or used in the methods and results. The researchers abided by the principle of confidentiality, and no incentive or monetary compensation was offered in return for participation.

3. Results

3.1. Item generation

A total of 110 studies (14 in Chinese and 96 in English) were included in the literature review, and we interviewed 13 participants to help identify additional items, which resulted in a 53-item item pool.

3.2. Delphi technique

A total of 14 experts in genetics, reproduction, ethics, and nursing education, with different academic qualifications and professional titles, participated in the first round of the Delphi process. Four genetic doctors, four genetic nursing experts, two reproductive doctors, and two reproductive nursing experts who were engaged in front-line PGT clinical work provided practical guidance on the clinical aspects of questionnaire development.

Three rounds of expert evaluation were conducted in this study. The response rates for the three rounds of expert consultation were 100 %, 100 %, and 71.40 %, respectively, indicating that the experts were enthusiastic about participating. The CV values for the three rounds of expert consultation on the total questionnaire were 0.19, 0.17, and 0.15, and the Kendall's *W* values were 0.18, 0.24, and 0.24, respectively. The CV value for the three dimensions was 0.14–0.20, and the Kendall's W value was 0.16–0.29. The Kendall's *W* significance test results for the total questionnaire and each dimension were all <0.05, indicating that the coordination of experts' opinions were good. The results showed that the mean authority coefficient values were 0.92, 0.88, and 0.89, showing that the degree of expert authority was high, and the expert opinions were reliable.

The average value for the importance of each item in the first round was 3.50–4.93, the acceptance rate was 0.43–1.00, and the full-score rate was 0.14–0.93. Six items with a CV > 0.25, an acceptance rate of 80 %, and a full-score rate of 50 % were deleted. Eight abstruse items base on 2 or more knowledge points in a single item were deleted. Fourteen items with weak content pertinence and little significance were also deleted, but 17 items were added, and 23 items were modified. This resulted in 41 items in the first round of expert evaluation.

The average value of importance for each item in the second round was 3.36–4.71, the acceptance rate was 0.57–1.00, and the full-score rate was 0.14–0.86. One item with an average importance value < 3.5, a CV > 0.25, an acceptance rate <80 %, and a full-score rate <50 % was deleted. However, one item was added, and twenty-four items were modified, resulting in 43 items in the second round of expert evaluation. The average importance value for each item in the third round was 3.70–4.80, the acceptance rate was 0.70–1.00, and the full-score rate was 0.10–0.80. No items were deleted, but three items were modified. Three rounds of expert evaluation resulted in a final 43-item PGT-KAP-Q in Chinese, including 17 items for knowledge (K1–K17), 15 items for attitude (A1∼A15), and 11 items for practice (P1∼P11).

3.3. Samples

A total of 320 participants completed the PGT-KAP-Q. Most were female (n = 95.90 %), with a mean age of 34.1 years (SD = 5.0), were undergraduates (45.00 %), had married once (88.40 %), and had only experienced one ART treatment cycle with PGT (60.60 %; Table 2).

3.4. Item analysis

The results of the extreme value comparison showed that the CR values for all items and high/low-scoring groups were 4.84–15.47 ($p < 0.05$). The results of the correlation coefficient analysis showed that the Pearson correlation item-total values were 0.38–0.69 ($p < 0.05$), the knowledge item-total values were 0.13–0.83 ($p < 0.05$), the attitude item-total values were 0.11–0.78 ($p < 0.05$), and the practice item-total values were 0.22–0.81 ($p < 0.05$). The item-total Cronbach's α coefficient was 0.95, which was greater than or equal to the Cronbach's α coefficient after the item deletion. The factor analysis results showed that, for the K1–K17 items, communality values were 0.31–0.69 and the factor loadings were 0.55–0.83; for the A1–A15 items, the communality values were 0.24–0.68 and the factor loadings were 0.49–0.82; and for the P1–P11 items, the communality values were 0.37–0.65 and the factor loadings were 0.61–0.81 (Supplemental Table 1).

3.5. Validation analysis

3.5.1. Content validity

Nine experts were invited to evaluate the content validity. The results showed that the I-CVI for each item of the questionnaire was

Table 2
The characteristics of the participants ($n = 320$).

Characteristics	n (%)
Gender	
Female	307(95.90)
Age (year, mean ± SD)	34.14 ± 5.04
Marital status	
first marriage	283(88.40)
remarriage	37(11.60)
Education level	
Primary school and below	1(0.30)
Junior school	25(7.80)
Senior school	25 (7.80)
Technical secondary school or junior college	109(34.10)
Bachelor degree	144(45.00)
Master degree or above	16(5.00)
Number of PGT treatment cycle	
Did not enter the PGT treatment cycle	72(22.50)
1 cycle	162(60.60)
2–3 cycles	71(22.20)
>3 cycles	15(4.70)

0.78–1.00, the P_C was 0–0.07, and the K* was 0.76–1.00. The K* evaluation for each item was excellent, and the S-CVI/Ave of the questionnaire was 0.95, indicating that the consistency of the expert opinions was good and that the questionnaire had good content validity.

3.5.2. Structural validity

Prior to performing EFA, we derived a KMO value of 0.92 and a significant Bartlett's test of sphericity ($\chi 2 = 9903.48$, $p < 0.05$). Three common factors were extracted using principal component analysis and the maximum variance method, and the results of the factor analysis were consistent with the theoretical conception. The eigenvalues were 13.80, 5.59, and 2.95, respectively; the variance contribution rates were 32.10 %, 13.01 %, and 6.86 %, respectively; and the cumulative variance contribution rate was 51.97 %. The results for correlation analysis of the load matrix showed that all item loads were >0.4 (Table 3).

3.6. Reliability analysis

3.6.1. Internal consistency

The internal consistency of the 43-item PGT-KAP-Q was evaluated based on Cronbach's α coefficient, which, for the knowledge, attitude, and practice dimensions, were 0.94, 0.92, and 0.92, respectively, and for the total questionnaire, 0.95 (Table 4).

3.6.2. Split-half reliability

We halved the questionnaire items and tested the correlations among the evaluation results. The results showed that the split-half

Table 3
Factor loading form Varimax rotation of the 43-item KAP-PGT-Q (correlation analysis) (n = 320).

Item	Factor 1 (Knowledge)	Factor 2 (Attitude)	Factor 3 (Practice)
K10	**0.80**	0.15	0.16
K8	**0.79**	0.10	0.15
K12	**0.77**	0.11	0.17
K9	**0.76**	0.12	0.19
K15	**0.76**	0.09	0.13
K14	**0.75**	0.08	0.13
K13	**0.73**	0.05	0.06
K11	**0.73**	0.10	0.18
K5	**0.72**	0.14	0.09
K6	**0.71**	0.12	0.14
K16	**0.70**	0.14	0.19
K4	**0.69**	−0.02	0.15
K7	**0.68**	0.13	0.13
K1	**0.59**	0.15	0.17
K17	**0.59**	0.18	0.02
K2	**0.56**	0.05	0.18
K3	**0.52**	0.03	0.17
A11	0.07	**0.81**	0.08
A14	0.04	**0.80**	0.23
A10	0.07	**0.78**	0.12
A15	0.09	**0.75**	0.19
A4	0.16	**0.73**	0.21
A1	0.10	**0.72**	0.13
A13	0.10	**0.71**	0.28
A2	0.15	**0.68**	0.11
A3	0.14	**0.68**	0.17
A12	0.03	**0.64**	0.02
A9	0.19	**0.63**	0.22
A6	0.11	**0.54**	0.17
A8	0.09	**0.50**	0.15
A5	0.10	**0.49**	0.08
A7	0.07	**0.43**	0.19
P7	0.15	0.22	**0.77**
P4	0.27	0.17	**0.74**
P8	0.14	0.23	**0.72**
P6	0.30	0.19	**0.71**
P5	0.26	0.12	**0.70**
P11	0.06	0.23	**0.65**
P9	0.09	0.28	**0.64**
P1	0.33	0.23	**0.64**
P2	0.33	0.22	**0.64**
P3	0.30	0.15	**0.63**
P10	0.05	0.18	**0.61**

Note: The extraction method was principal component analysis, and the rotation method was the maximum variance method.

reliability for KAP was 0.80–0.89, and the split-half reliability for the total questionnaire was 0.76 (Table 4).

3.6.3. Test–retest reliability

In this study, 50 subjects were retested (T2) 14 days after completing the first assessment (T1), and we calculated the test–retest reliability coefficients for each dimension and the total questionnaire for 40 valid questionnaires. The results showed that the KAP test–retest reliability coefficients were 0.45–0.82 ($p < 0.05$), and the test–retest reliability coefficient for the total questionnaire was 0.78 ($p < 0.05$; Table 5).

4. Discussion

4.1. Significance and application of the PGT-KAP-Q

The rapid development of PGT may have exceeded the understanding of genetic counselees with PGT indications regarding their reproductive choices [7]. Few studies have examined the PGT KAP of genetic counselees with PGT indications in China, and the research tools used have not demonstrated good reliability and validity. The aim of this study was to develop and evaluate a PGT-KAP-Q to enable hospital nurses to understand the KAP of genetic counselees with PGT indications, analyze their existing problems and needs according to the questionnaire results, and propose targeted interventions to supplement counselees' relevant knowledge and promote positive behaviors that will benefit the health of the next generation. In addition, this questionnaire may also be used as an evaluation tool to assess the effect of publicity and education campaigns in subsequent research with the aim of improving campaign strategies, content, and planning.

4.2. Expert correspondence for item revision

In the first round of expert evaluations regarding the revision of items, the CV for P8 ("I actively discuss with other couples who have (or will have) preimplantation genetic testing (PGT) technology to assist pregnancy") was >0.25, the acceptance rate was <80 %, and the full-score rate was <50 %. However, studies have shown that ART patients have specific communication needs [34,35], and we hoped that, based on clinical observations and the results of the qualitative interviews in this study, genetic counselees with PGT indications would be able to exchange PGT-related information with other patients. Therefore, the research team decided to retain and further modify P8 to evaluate their communication behavior. In the second round of expert evaluations, the CV for A1 ("I hope to acquire relevant knowledge of preimplantation genetic testing (PGT) technology") was >0.25, the acceptance rate was <80 %, and the full-score rate was <50 %. However, according to the qualitative interview results, genetic counselees with PGT indications have differing levels of PGT knowledge. Following the discussion, the research group decided to retain and further modify the A1 item to evaluate their learning attitudes.

4.3. The rigorous item selection

In this study, we used extreme value comparison to screen for item discrimination. Generally speaking, if the CR of items is less than 3, or the difference in the *t*-test results is not statistically significant ($p > 0.05$), items should be deleted [23]. The results of our study showed that the CR values for all items and the high/low-scoring groups were >3 with $p < 0.05$, indicating that the item discrimination is quite good.

We used the correlation coefficient method to screen for the representativeness and independence of items. The Pearson correlations for the item totals, and between each item and its relevant dimension total, should be < 0.3 ($p > 0.05$) and <0.4 ($p > 0.05$), respectively, to indicate that the items are not representative [24,25]. Our results showed that the Pearson correlation item totals for all items were >0.3 ($p < 0.05$), and the Pearson correlation between each item and its relevant dimension total was >0.4 ($p < 0.05$), indicating that all items were representative. The Pearson correlations between each item and the other dimension totals should be > 0.4 ($p > 0.05$) to indicate that the items have poor independence [25]. Our results showed that the Pearson correlations between each item and the other dimension totals were <0.4 ($p < 0.05$), indicating that the items have good independence.

4.4. Reliability and validity

We used validity analysis to assess the correctness and authenticity of the questionnaire: the better the validity of the questionnaire, the smaller the deviation between its measured value and the real target value. We employed reliability analysis to evaluate the

Table 4
Cronbach's α coefficient and split half reliability of each dimension and total questionnaire (n = 320).

	Item number	Scores ($\bar{x} \pm s$)	Cronbach's α coefficient	split half reliability
Knowledge	17	35.47 ± 8.54	0.94	0.89
Attitude	15	61.44 ± 7.34	0.92	0.80
Practice	11	37.02 ± 8.28	0.92	0.80
Total	43	133.93 ± 19.11	0.95	0.76

Table 5
Test-retest reliability of each dimension and total questionnaire (n = 40).

	First test (T_1, $\bar{x} \pm s$)	Retest (T_2, $\bar{x} \pm s$)	test-retest reliability coefficient	*P*
Knowledge	35.05 ± 8.05	36.83 ± 6.74	0.82	<0.01
Attitude	62.35 ± 5.45	61.00 ± 5.55	0.45	<0.01
Practice	37.45 ± 7.42	36.03 ± 7.46	0.64	<0.01
Total	134.85 ± 17.00	133.85 ± 15.89	0.78	<0.01

reliability/stability of the questionnaire: the better the reliability of the questionnaire, the smaller the measurement of standard error [27].

We used a content validity index to evaluate the content validity of the questionnaire. It is generally believed that a K^* value of 0.60–0.74 is good, and greater than 0.74 value is excellent [23,30]: the higher the K^* value, the greater the I-CVI, and the higher the consistency of expert opinions [30]. An I-CVI ≥0.78 and an S-CVI/Ave ≥0.90 suggest good content validity [23]. The results of this study showed that the I-CVI for each item of the questionnaire was >0.78, the K^* for each item was >0.74, meaning that the K^* evaluation for each item was excellent, and the S-CVI/Ave for the questionnaire was 0.95, indicating the consistency of expert opinions and that the content validity is good.

We used EFA to evaluate the structural validity of the questionnaire. It is generally believed that if the cumulative contribution rate of the extracted common factors exceeds 50 %, and the factor loading for each item on its corresponding common factor is > 0.4, the questionnaire has better structural validity [20]. A significant Bartlett spherical test ($p < 0.05$) and KMO value > 0.9 (KMO = 0.915) meant that the data was very suitable for factor analysis [20], and the cumulative variance contribution rate was >50 %. We extracted three common factors related to KAP through principal component analysis and the maximum variance method. The results of the factor analysis were consistent with the theoretical conception. The load matrix results for the correlation analysis showed that the load of all items on the corresponding factor was >0.4, indicating that the questionnaire has good structural validity.

We used Cronbach's α coefficients to evaluate the internal consistency of the questionnaire. The results showed that the Cronbach's α coefficients for the total questionnaire and for each dimension were 0.92–0.95. The Cronbach's α coefficient for the knowledge dimension was 0.94, similar to the PGT knowledge questionnaire developed by Mo Fengyi et al. [12] (Cronbach's α coefficient 0.934) but higher than that developed by Gietel-Habets et al. (Cronbach's α coefficient 0.72) [7]. It is generally believed that a Cronbach's α value ≥ 0.9 indicates excellent internal consistency [32]. Therefore, the KAP-PGT-Q and each dimension have good internal consistency.

The split-half reliability results of this study showed that the split-half reliability for the KAP dimensions was 0.80–0.89, and the split-half reliability for the total questionnaire was 0.76. It is generally believed that a split-half reliability >0.7 indicates better homogeneity of the questionnaire [23]. Therefore, the KAP-PGT-Q has good homogeneity.

The test–retest reliability results of this questionnaire showed that the test–retest reliability coefficient for each KAP dimension was 0.45–0.82 ($p < 0.05$), and the test–retest reliability coefficient for the total questionnaire was 0.78 ($p < 0.05$). It is generally believed that the test–retest reliability for each dimension should be above 0.7 to indicate good test–retest reliability [33]. The test–retest reliability for the total questionnaire and the knowledge dimension of the questionnaire were greater than 0.7, indicating that the total questionnaire and the knowledge dimension items were consistent and stable. However, the test–retest reliability of the attitude and practice dimensions was low, and the average scores for the attitude and practice dimensions in the second measurement were lower than those in the first measurement, possibly due to a change in the subjects' attitudes toward PGT before the second measurement, which may have affected their behavior. In addition, the average score for the knowledge dimension in the second measurement was higher than that in the first measurement, perhaps because the participants paid more attention to the questions after the first test. This may reflect the fact that the knowledge items in the KAP-PGT-Q were accepted by the participants to a certain extent and had a certain degree of pertinence to the knowledge dimension.

In conclusion, this questionnaire has good content and structural validity, showing that it can reflect the PGT KAP levels of genetic counselees with PGT indications. The questionnaire is also consistent and stable, and it can be popularized for use with genetic counselees who have PGT indications.

5. Limitations

Several limitations are acknowledged in this study. First, most of the participants were females, these could represent a limit for this study, because the wives always have more time and are more willing to participant in this study. Besides, this questionnaire was validated among Chinese genetic counselees with PGT indications in a single center with small sample, and due to the different environment and culture may not be appropriate for populations in other countries. Hence, this instrument would benefit from validation and modification, in different populations and settings.

Second, we were not able to assess the concurrent validity due to the absence of previously validated instruments, or gold standard, to which we could compare our instrument. While the psychometric indicators our study used are robust, validity could be enhanced if examined in greater detail, in conjunction with concurrent and predictive validity. Additionally, confirmatory factor analysis (CFA) to test if data fits the hypothesized three-factor structure derived from this EFA will be examined later. Additionally, given the 95 % confidence interval used for test-retest reliability in this study, future studies could explore narrower confidence intervals with larger sample sizes to lend greater reliability to the findings. The results of the study showed a high degree of internal consistency within the

measure. It also suggests that future studies may be interested in exploring the development of a shorter version.

Third, according to extensive review of literature, many studies have examined self-designed questionnaires and only few have reported their reliability and validity. No study has reported their item selection. We compared the reliability and validity as possible in this study, and future research could examine the questionnaire in more depth.

6. Conclusion

Birth defects and genetic diseases have serious adverse effects on individuals, families, and society. The rapid development of PGT may have outpaced the awareness of reproductive choices among genetic counselees with PGT indications. Although some studies have reported on the PGT knowledge and attitudes of genetic counselees with PGT indications, most of them have examined self-designed questionnaires that fail to meet questionnaire design and statistical measurement evaluation standards. For the first time, based on the KAP model, we compiled a PGT-KAP-Q for genetic counselees with PGT indications in line with the standard questionnaire development guidelines and methodologies [22], and the reliability and validity met the requirements for statistical measurement. The KPA-PGT-Q for genetic counselees with PGT indications that we developed in this study, consisting of 43 items across 3 dimensions, has good reliability and validity. The number of items is moderate, the language is easy for patients to accept and understand, and the questionnaire can be used for clinical research and applications.

Compliance with ethical standards

Conflicts of interest

Author Zhen Luo, Author Chaofeng Tu, Author Li Li and Author Lingli Peng declare that they have no conflict of interest.

Human studies and informed consent

Animal Studies: No animal studies were carried out by the authors for this article.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethics declarations

This study was reviewed and approved by the ethics committee of the Reproductive and Genetic Hospital of CITIC-Xiangya, with the approval number: LL–SC–2022-003. All participants/patients (or their proxies/legal guardians) provided informed consent to participate in the study. Consent was implied with completion of the anonymous survey. All procedures performed were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

CRediT authorship contribution statement

Zhen Luo: Writing – review & editing, Writing – original draft, Validation, Supervision, Software, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation. **Chaofeng Tu:** Visualization, Supervision, Investigation, Funding acquisition. **Li Li:** Resources, Project administration, Methodology, Conceptualization. **Lingli Peng:** Writing – review & editing, Visualization, Resources, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e34945.

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