USING COGNITIVE INTERVIEWS TO REFINE A PATIENT-REPORTED OUTCOME MEASURE OF SEXUAL EXPERIENCES IN WOMEN WITH TYPE 1 DIABETES

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Background
Patient-reported outcome measures (PROMs) should accurately capture the experiences and perspectives of the target population. Cognitive interviewing is a key stage in PROM development, providing evidence of content validity by evaluating how respondents understand, process and answer questionnaire items. This study reports the cognitive interview phase undertaken during the development of the Female Sexual Experience in Diabetes Type 1 (FSEDiT-1)**,** a PROM designed to assess the sexual experiences of women living with type 1 diabetes.

Aim
To evaluate the clarity, comprehensibility, relevance and interpretability of the FSEDiT-1 items and refine the questionnaire based on participant feedback.

Methods
A qualitative cognitive interviewing approach was used. Women with type 1 diabetes were recruited through purposive sampling via social media platforms. Cognitive interviews were conducted between May and June 2024 using a combination of think-aloud techniques and concurrent verbal probing, enabling participants to explain their thought processes while responding to each questionnaire item. Interviews explored participants' comprehension of the questions, retrieval of relevant information, judgement when selecting responses, and the overall acceptability of the questionnaire. Data were analysed using the text summary method, with findings organised within a structured matrix to identify issues requiring modification. Revisions were made iteratively across three rounds of interviews.

Results
Thirteen women participated across three rounds of cognitive interviews: five in the first round, five in the second, and three in the final round. The first round evaluated 34 questionnaire items. Minor revisions were made to nine items, primarily involving wording, clarity and the comprehensiveness of specific terms. Following these revisions, the second round identified three additional items requiring minor refinement. The final round confirmed that the revised questionnaire was well understood, relevant and acceptable to

participants, with no substantial concerns regarding interpretation or response options.

Conclusions

Cognitive interviewing proved to be an essential component of the FSEDiT-1 development process. Participant feedback informed iterative refinements that enhanced the clarity, relevance and content validity of the questionnaire. The findings support the acceptability of the FSEDiT-1 among women with type 1 diabetes and demonstrate the value of cognitive interviewing in developing robust, patient-centred PROMs.