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Clean intermittent catheterisation determinants and caregiver adherence in paediatric patients with spinal dysraphism and spinal cord injury in a paediatric spinal differences clinic: a mixed methods study protocol

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ABSTRACT

Introduction Clean intermittent catheterisation (CIC) is the standard of care for treating neurogenic lower urinary tract dysfunction (NLUTD), the most common bladder dysfunction in children diagnosed with spinal dysraphism (SD) and spinal cord injury (SCI). Failure to follow the prescribed CIC regimen results in urinary tract infections, incontinence and renal insufficiency. Adherence to CIC is suboptimal, with reported non-adherence rates of 18%–66%. Despite the efficacy of CIC, the research on CIC adherence is not well defined in the literature and even less for caregivers of children on CIC protocols.

Methods This proposed study aims to identify caregiver CIC adherence and determinants while exploring the personal experiences of performing CIC from the perspective of caregivers of children with NLUTD due to SD and SCI. This cross-sectional, correlational, convergent mixed methods study design in which qualitative and quantitative data will be collected simultaneously will be used to study the level of adherence and the relationship of caregiver determinants to CIC in children with SD and SCI and adherence to the CIC protocol. Convenience sampling will be used to identify 60 adult caregivers who can read and write English or Spanish and have a child diagnosed with SD and SCI who is currently prescribed CIC by a urology provider.

Analysis The adherence data will be reported as frequency and percentages. A correlation analysis will be computed to assess the association between determinants measured by the Clean Intermittent Catheterization-Caregiver Questionnaire and adherence levels measured with the Intermittent Catheterization Adherence Scale. Thematic analysis will be used to analyse and interpret the interview data. A comparison joint display will be developed to compare quantitative and qualitative data results.

Ethical and dissemination Institutional review board approval was obtained from the Children's Mercy Kansas City (Study00003003) and the University of Missouri-Kansas City (#2100185). The study's main results will be disseminated to caregiver participants, published in peer-reviewed journals and presented at conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study design is supported by the paediatric self-management conceptual framework and the adherence framework.
⇒ The mixed methods design will be used to gain deeper insight into caregiver experiences in performing clean intermittent catheterisation by maximising strengths in both quantitative and qualitative designs.
⇒ The single clinical setting may limit the generalisability of the results.
⇒ Self-report measures may introduce bias and inaccuracies to the data.

INTRODUCTION

Neurogenic lower urinary tract dysfunction (NLUTD) is a condition that impacts 70%–95% of individuals diagnosed with spinal dysraphism (SD) and spinal cord injury (SCI) worldwide.[1 2] SD is a spectrum of neurologic disorders resulting from abnormal development of the ectodermal, mesodermal and neuroectodermal tissues, adversely affecting brain, bone, extremities and bowel and bladder functions.[3] Traumatic SCI is defined as a lesion on the spinal cord that results in the disruption of nerve fibres due to a traumatic event.[4] SD occurs in 1–5 cases per 1000 live births, whereas SCI occurs in 10.5 cases per 100 000 people globally.[3 4] Depending on the location of the spinal anomaly or injury, symptoms of NLUTD may impair urinary storage, which can cause renal insufficiency, urinary tract infections (UTIs) and incontinence.

Clean intermittent catheterisation (CIC), introduced as a treatment option in the 1970s and currently the gold standard for

the treatment of NLUTD, involves the insertion of a catheter into the bladder to drain the urine, after which the catheter is removed.[5] This procedure is important for bladder drainage as part of a comprehensive programme to facilitate safe storage pressures and, therefore, preserve kidney health. Failure to adhere to CIC protocols increases the likelihood of adverse patient health outcomes (eg, renal insufficiency, incontinence and UTIs) and drives up healthcare costs, often due to increased emergency department and urgent care visits.[6] Medical expenditures in the USA for patients with NLUTD have been estimated at US$147 million per year, a total that includes the 94% of emergency department visits that are related to UTIs.[7]

CIC treatment protocols are complex, time-sensitive and repetitive.[8] Individuals on CIC protocols follow a multitude of steps when executing CIC. Most adults on CIC protocols self-catheterise, but in the paediatric population, most children (school age and younger) are dependent on caregivers (parents, guardians, grandparents and siblings) to perform CIC. Individuals responsible for performing CIC face many challenges, including technical difficulties when performing CIC (visualisation of urethra and positioning), preparation and cost of equipment (catheter and lubrication), time (following recommended timed intervals) and emotional burden (stress of urinary health and continence).[9] Catheterisation may be prescribed 6–8 times daily, delivered every 2–3 hours in the home and community setting. Studies of adherence to CIC report suboptimal rates, ranging widely from 18% to 66%.[6 10 11] Though this complex, intensive treatment creates psychological, emotional and financial demands on the caregivers who deliver CIC,[6 11 12] little attention has been paid to the determinants (factors hindering adherence to CIC) and experiences of caregiver CIC adherence, creating a gap in the determinants that influence CIC and how well the experience is understood. The few studies that explored caregivers' adaptation to CIC protocols identified determinants as lack of family and healthcare team support, lack of time to adjust to the new protocol and initiation of CIC at an older age.[13 14] The literature on caregiver CIC determinants also underrepresents minority sociodemographic groups diagnosed with SD.[15]

Adherence is defined as 'the extent to which a person's behaviour, medication taking, following a diet and executing lifestyle changes corresponds with agreed recommendations from a healthcare provider'.[16] Adherence to a treatment plan such as CIC involves initiation of the behaviour, execution of the behaviour and persistence in the behaviour.[17] Initiation is when the patient/caregiver starts the prescribed protocol, execution is the degree to which the patient/caregiver's actual behaviour corresponds with the prescribed protocol, and persistence is the period from the initiation of the prescribed protocol to the time point where the patient/caregiver stops the protocol.[17]

Aims/research questions

Research rigour is suboptimal, with a paucity of evidence on barriers and facilitators to caregiver adherence to CIC in paediatric patients. Very few studies evaluate interventions to improve caregiver adherence. Additionally, there is a lack of consistent measures for caregiver adherence to CIC in this group. This study will provide the foundational evidence to address these gaps.

The purposes of this study are (1) to describe the level of caregiver adherence to CIC in children with SD and SCI, (2) to explore the predictive relationship between caregiver demographics and determinants to CIC and adherence to the CIC protocol in children with SD and SCI and (3) to determine how personal experiences with CIC influence caregivers' adherence behaviours. The primary aim of this study is to quantify the level of CIC adherence of caregivers of paediatric patients with SD and SCI. The secondary aim is to evaluate the relationship between caregiver demographics and CIC determinants and adherence to CIC. The third aim is to evaluate caregivers' perceptions of determinants of CIC adherence in paediatric patients with SD and SCI.

The following are research questions proposed: (1) What is the level of caregiver adherence to CIC in children with SD and SCI? (2) What is the relationship between caregiver determinants to CIC and adherence to CIC in children with SD and SCI? (3) What are the differences among perceived caregiver determinants between caregivers who adhere to their children's CIC protocol and caregivers who are non-adherent to their children's CIC protocol? and (4) What are the caregivers' experiences of performing CIC on a child with SD and SCI? The first hypothesis is that caregivers with a lower level of determinants will have higher CIC adherence levels than caregivers with a higher level of determinants. The second hypothesis is that differences will exist among perceived caregiver determinants, caregivers who adhere to their children's CIC protocol and caregivers who are non-adherent to their children's protocol.

METHODS

Study design

A cross-sectional, correlational, convergent mixed methods study design, in which qualitative and quantitative data will be collected simultaneously, will be used to study the level, determinants and experience of caregiver CIC adherence in children with SD and SCI and adherence. A mixed methods approach will be well suited to increase our understanding of the complexities surrounding the experience of caregiver CIC adherence when caring for children with SD and SCI by generating richer data than could be obtained from either a quantitative or qualitative approach alone.[18]

Sample and setting

Adult caregivers who are responsible for their child's CIC protocol will be recruited from the spinal differences

clinic (SDC) at a paediatric institution located in Midwest region of the USA. Questionnaire data will be collected on CIC adherence levels and determinants. Interview data will be generated describing caregiver personal experiences with CIC. Convenience sampling will be used to identify 60 caregivers who meet the following inclusion criteria: (1) age 18 years or older, (2) caregiver of a child diagnosed with SD or SCI, (3) having a child currently prescribed CIC under the care of a urology provider and (4) able to read and write English or Spanish. There are no exclusion criteria.

A sample size of 60 participants was chosen based on feasibility and statistical considerations. For an alpha level of 0.05, a sample of 60 provides 80% power for a test of a medium correlation coefficient of 0.35. Since 20 potential caregiver participants bring their children to the SDC each week and 14 of these caregivers are anticipated to meet eligibility criteria, with a 40% consent rate based on the principal investigator (PI's) recruitment experiences from other active studies, 5 caregivers will be recruited each week.[19] Therefore, it will take 12 weeks to achieve the study recruitment goal of 60 caregiver participants for the study. Stratified sampling of 10 of the 60 participants will be used to ensure participants from diverse backgrounds are invited to share their experiences (see online supplemental appendix 1).

There is limited data from which conclusions can be drawn regarding race and/or ethnicity of caregivers of children with SD and SCI in the USA. Data indicate the ethnic demographics of 89% white, 5.8% Hispanic, 1.6% black, 1.8% Asian and 1.8% other.[20] The caregiver's race and/or ethnicity may differ from their children. Recruitment goals will include 48 (96%) women, 40 (80%) white non-Hispanic, 6 (12%) Hispanic, 1 (2%) black, 2 (4%) Asian and 1 (2%) other to represent the gender and ethnic diversity of the national population. Data will be tracked in an ongoing fashion in the study by the PI, and if minority recruitment is substantially different than planned, additional recruitment outreach strategies will be employed. For example, a clinic team member with similar racial and/or ethnic characteristics of the group in which the enrolment is lagging will be recruited to join the study team.

Measures/instruments

Demographics

The PI will collect the following demographic information from caregivers: age, race, ethnicity, marital status, education, income, number of children in the home, age of children in the home and geographic location. Based on the paediatric self-management framework, the modifiable and non-modifiable influences were considered when selecting demographic information to collect.[21]

Clean Intermittent Catheterization-Caregiver Questionnaire (CIC-cgQ)

Determinants of caregiver adherence will be measured by the CIC-cgQ.[19] The CIC-cgQ has 25 questions scored using a 5-point Likert scale with response options from 1 for strongly disagree to 5 for strongly agree. Scores on the CIC-cgQ range from 25 to 125, with higher scores indicating fewer determinants.[19] The determinants measured with this tool include technique, psychological burden and timing burden.[19] The questionnaire takes about 10 min to complete. Cronbach's alpha for CIC-cgQ was 0.84, indicating high internal consistency reliability. Criterion-related validity was supported using known groups to assess success or difficulty with CIC.[19]

Intermittent Catheterization Adherence Scale (ICAS)

Caregiver CIC adherence will be measured by the ICAS.[22] The scale has eight questions that are answered by the caregiver as either 'yes' or 'no' resulting in a score of 0–8.[22] The patients' score is classified into 3 intervals with 0=strong adherence, 1–2=average adherence and 3–8=low adherence. The questionnaire takes about 5 min to complete. Cronbach's alpha for the ICAS was 0.73, indicating high internal consistency reliability.[22] Eight days after the initial test, test–retest reliability, where the participants again completed the questionnaire, resulted in an intraclass correlation coefficient (ICC) of 0.74.[22] A Pearson's correlation coefficient of $p<0.05$ supported the construct validity by comparing both the Intermittent Catheterization Difficulty Questionnaire and the Intermittent Catheterization Satisfaction Questionnaire with ICAS.[22]

Interview guide

One in-person semistructured interview conducted by the PI, lasting approximately 30 min, will be conducted with 10 participants. Purposive sampling will be used to select qualitative participants that will seek to answer the research question of the experiences of caregivers responsible for their children with SD and SCI CIC protocol. The number of participants was determined based on this study's homogeneous population and narrowed objectives.[23] The interviews will be minimally structured to encourage participants to expand on their ideas.[24] Follow-up probes will be posed to facilitate full, detailed responses and clarify information (see online supplemental appendix 2). Interviews will be audio recorded on a digital voice recorder, and observations to capture nonverbal cues will be recorded in post-interview field notes.

The PI is a clinician in the SDC and has previous exposure to participants through the clinic, which prompted her interest in the topic. Several steps will be taken to increase the rigour of the qualitative portion of this study.[25] The research data will be collected from multiple sources to enhance credibility. Collecting interview and observation data will allow for a complete description of the content and context of the caregivers' experiences. To enhance confirmability, the PI will check and recheck data throughout the study. The PI will report as much of the participants' words and descriptive details from the interviews as possible to convey the caregivers' experiences and account for the everchanging context

where the research occurs to increase the study's dependability.[26] Using participants' language in qualitative research promotes rigour in qualitative work by providing readers with detail for determining whether findings are transferable to other contexts or groups.[25] The PI will enhance transferability by providing ample detail about the context of individual cases so others can determine if the situations apply elsewhere.

Data collection

Following institutional review board approval, the PI will meet with the SDC staff during a weekly staff meeting and provide study details and laminated inclusion pocket cards for their convenience in identifying prospective participants. During the child and caregiver's clinic visit, the clinic healthcare providers and nurses will inform caregivers who meet the inclusion criteria about the study and ask if they are willing to meet with the PI on the day of their visit. This procedure avoids the hazard of undue coercion since the PI is part of the clinical team. The PI will be present each day of the SDC to answer any questions about the study by the clinic providers and nurses and to keep the study recruitment at the forefront of their daily work.

Prospective participants who agree to meet with the PI will be directed to a private room located at the clinic, where the PI will introduce herself to the potential participant and provide a verbal and written explanation of the study's purpose, procedures, potential benefits, risks, possible scientific gains and participation honoraria. The PI will review the participants' rights and emphasise the voluntary nature of participation in the study. The potential participant will be informed that participation in the study could be terminated at any point and that participation or non-participation would not influence their child's care at the SDC. The PI will answer any potential participant questions about the study. If the individual agrees to be in the study, the PI will review the consent and Health Insurance Portability and Accountability Act forms and obtain written informed consent. Next, the PI will electronically collect demographic information and administer the CIC-cgQ to measure determinants and the ICAS to measure adherence to CIC via Research Data Capture (REDCap).[27] The measures will be reviewed for completeness by the PI, and if any answers are left incomplete, the PI will confirm with the participant that they were intentionally left blank. If the participant is one of the 10 selected for an interview, the PI will conduct the semistructured interview using the interview guide to complete the study visit. The PI will collect all data to ensure consistency with data collection. All participants will be provided an honorarium for their contribution to the study as compensation for their time.

Data analysis

REDCap will be used to store data.[27] Data analysis will be conducted using R statistical software under the direction of the biostatistician.[28] The PI will take all measures to ensure all data points are collected; however, if missing data are more than 10% in this study, multiple imputation techniques will be employed to guarantee the best statistical analysis results. Frequencies, percentages, means, ranges and SD will be reported for demographic data.

Research question 1

What is the percentage of caregivers with low, average and high adherence to CIC in children with SD and SCI?

Analysis plan

The ordinal level adherence data will be reported as percentages. For example, if caregivers answer yes to 3–8 questions, the adherence level will be *low adherence*. If caregivers answer yes to 1–2 questions, the adherence level will be *average adherence*. If the caregivers do not answer yes to any questions, then the adherence level will be *strong adherence*.

Research question 2

What is the correlation between caregiver determinants to CIC and adherence levels to CIC in children with SD and SCI?

Hypothesis

Caregivers with a lower level of determinants will have higher CIC adherence levels than caregivers with a higher level of determinants.

Analysis plan

The determinant scores of the CIC-cgQ had a possible composite range of 25–125, with higher scores representing greater determinants of CIC. The CIC-cgQ identifies four unique factors emerging from responses to the items: (1) ease of use, (2) convenience, (3) discreetness and (4) psychological well-being. Reverse coding will be applied to the items negatively worded. The mean sum of each question will be used to calculate the composite score to keep the scores along the same continuum as the response anchors to avoid inflation of scores through addition and to avoid skewing accounting for possible missing responses on some items. Furthermore, the mean sum of questions within the four domains will calculated to better understand the association with CIC adherence between the different types of determinants.

The sample will be analysed for normal distribution with a Shapiro-wilk test to determine if a parametric or a non-parametric analysis to assess the relationship between determinants measured with the CIC-cgQ and adherence scores measured with the ICAS would be appropriate. If the assumption of normality is met for the distribution of the adherence level scores measured with the ICAS, a Pearson's correlation coefficient will be computed to assess the association between perceived determinants measured with the CIC-cgQ (independent variable) and the adherence levels (dependent variable). If the assumption of normality is not met for the distribution of the adherence level scores measured with the ICAS, a Spearman's rho correlation coefficient will be computed

to assess the association between perceived determinants measured with the CIC-cgQ and the adherence levels.

Research question 3

What are the differences in perceived caregiver determinants between caregivers in low, average and high adherence groups?

Hypothesis

Differences will exist among perceived caregiver determinants between caregivers in low, average and high adherence groups.

Analysis plan

The sample will be analysed for normal distribution with a Shapiro-wilk test to determine if a parametric or a non-parametric analysis will be used to assess the difference among perceived caregiver determinants between caregivers in low, average and high adherence groups. If the assumption of normality is met for the distribution of the adherence level scores measured with the ICAS, an analysis of variance test will be computed to compare the group differences in perceived caregiver determinants scores measured by the CIC-cgQ across the three groups of low, average and high adherence. If the assumption of normality is not met for the distribution of the adherence level scores measured with the ICAS, the Kruskal-Wallis test will be computed to compare the group differences in perceived caregiver determinants scores measured by the CIC-cgQ across the three groups of low, average and high adherence.

Research question 4

What are the caregivers' experiences of performing CIC on a child with SD and SCI?

Analysis plan

Thematic analysis will be used to analyse and interpret the data.[29] The PI and research assistant will transcribe interviews using Dedoose and check against recordings for accuracy prior to analysis.[30] The PI (AW) and study team member (CLR) will then review the transcripts, interview observations and field notes for overall sense and preliminary themes.[29] Preliminary themes from interviews and observations will be charted into mind maps and reduced to descriptive themes.[31] Passages exemplifying the themes will be selected for reporting by the PI and the study team members.

Data integration plan

A comparison joint display will be developed to compare quantitative and qualitative data results. The PI will further consider how the confirming, disconfirming and expanded results provide insight into the determinants of CIC adherence experienced by caregivers of children with SD and SCI and aim to answer quantitative, qualitative and mixed methods research questions.[23]

Limitations

Limitations of the proposed study include the single site and clinical setting. The single site, situated in a city in a midwestern state, means that influences characteristic of geographic and demographic settings could be missed in this study. The single clinical setting means that only caregivers whose children have appointments in the clinic would have the potential to be interviewed. Caregivers who perform CIC but avoid or cannot use the clinic for various reasons may have important and systematically overlooked challenges that this study will not capture. The study team will attempt to limit the effects of the first by providing ample detail about the context of individual cases so a reader can determine if the situations apply elsewhere. Furthermore, the participants are purposefully included to represent the national sample of gender and ethnic diversity. Finally, the study's complex nature brings the possibility that participants may view the PI as the healthcare provider managing their child's disease and not a researcher. This could result in partial disclosure of their experiences. To prevent this situation, at the time of the interview, the PI will disclose their role as researcher and not as the child's clinical provider.

ETHICS AND DISSEMINATION

Institutional review board approval for the study has been obtained from Children's Mercy Kansas City (Study 00003003) and the University of Missouri-Kansas City (# 2100185). The main risk of this study is loss of confidentiality. The risk will be minimised by careful collection and storage of data. The study participants' confidentiality will be maintained using the following techniques: (1) PI will be responsible for all data management, (2) the data will be entered into a multiuser electronic database, REDCap, programmed to track data entry and modifications, (3) the database will be password protected and encrypted and backup copies will be maintained and (4) all participants' names and other protected health information identifiers will be removed from the data on assignment of a study identification code.[26] The informed consent forms will be stored separately from the study data in a password-protected electronic file. Only aggregate data will be reported. There are no direct diagnostic or therapeutic benefits to subjects participating in this research. Participation is voluntary.

The study's main results will be disseminated to caregiver participants and will seek participant involvement in dissemination methods. Furthermore, study results will be published in peer-reviewed journals and presented at national and international conferences.

Contributors AW: study conception and draft manuscript preparation. CLR and JMG: draft manuscript preparation. All authors reviewed the results and approved the final version of the manuscript. AW and JMG are guarantors.

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Competing interests None declared.

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REFERENCES

1 Guerra L, Leonard M, Castagnetti M. Best practice in the assessment of bladder function in infants. *Ther Adv Urol* 2014;6:148–64.
2 Patel DN, Alabastro CG, Anger JT. Prevalence and Cost of Catheters to Manage Neurogenic Bladder. *Curr Bladder Dysfunct Rep* 2018;13:215–23.
3 Lu VM, Niazi TN. Pediatric Spinal Cord Diseases. *Pediatr Rev* 2021;42:486–99.
4 Kumar R, Lim J, Mekary RA, *et al*. Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume. *World Neurosurg* 2018;113:e345–63.
5 Lapides J, Diokno AC, Silber SJ, *et al*. Clean, Intermittent Self-Catheterization in the Treatment of Urinary Tract Disease. *J Urol* 2017;197.
6 Cooper J, Chisolm D, McLeod DJ. Sociodemographic Characteristics, Health Literacy, and Care Compliance in Families With Spina Bifida. *Glob Pediatr Health* 2017;4:2333794X17745765.
7 Palma-Zamora ID, Atiemo HO. Understanding the Economic Impact of Neurogenic Lower Urinary Tract Dysfunction. *Urol Clin North Am* 2017;44:333–43.
8 Pinder B, Lloyd AJ, Elwick H, *et al*. Development and psychometric validation of the intermittent self-catheterization questionnaire. *Clin Ther* 2012;34:2302–13.
9 Faleiros F, Pelosi G, Warschausky S, *et al*. Factors Influencing the Use of Intermittent Bladder Catheterization by Individuals With Spina Bifida in Brazil and Germany. *Rehabil Nurs* 2018;43:46–51.
10 Bolinger R, Engberg S. Barriers, complications, adherence, and self-reported quality of life for people using clean intermittent catheterization. *J Wound Ostomy Continence Nurs* 2013;40:83–9.
11 Lim S-W, Lee H-E, Davis M, *et al*. Perceived barriers and difficulties of intermittent catheterization: In Korean patients with spinal dysraphism and their parents. *Neurourol Urodynam* 2016;35:395–9.
12 Borzyskowski M, Cox A, Edwards M, *et al*. Neuropathic bladder and intermittent catheterization: social and psychological impact on families. *Dev Med Child Neurol* 2004;46:160–7. Available: https://doi.org/10.1017/S0012162204000295
13 Flewelling KD, Wengryn DM, Buchanan CL, *et al*. Unexpected challenges faced by caregivers of children with neurogenic bladder: A qualitative study. *J Pediatr Urol* 2022;18:S1477-5131(22)00270-4.
14 Bauer SB, Saunders RA, Masoom SN, *et al*. The art of introducing clean intermittent catheterization: How families respond and adapt: A qualitative study. *Neurourol Urodyn* 2023;42:309–21.
15 Wilpers A, Lynn AY, Eichhorn B, *et al*. Understanding Sociodemographic Disparities in Maternal-Fetal Surgery Study Participation. *Fetal Diagn Ther* 2022;49:125–37.
16 Sabaté E, World Health Organization. *Adherence to long-term therapies: evidence for action*. Geneva: World Health Organization, 2003.
17 Vrijens B, Geest S, Hughes DA, *et al*. A new taxonomy for describing and defining adherence to medications: New taxonomy for adherence to medications. *Br J Clin Pharmacol* 2012;73:691–705. Available: https://doi.org/10.1111/j.1365-2125.2012.04167.x
18 Johnson RB, Onwuegbuzie AJ, Turner LA. Toward a Definition of Mixed Methods Research. *J Mix Methods Res* 2007;1:112–33.
19 Wickham A, McElroy SF, Bowlin P, *et al*. Testing and validation of the CIC-cgQ and CIC-childQ in paediatric patients and their caregivers. *J Urol Nurs* 2021;15:77–81.
20 Sadighian MJ, Allen IE, Quanstrom K, *et al*. Caregiver Burden Among Those Caring for Patients With Spina Bifida. *Urology* 2021;153:339–44.
21 Modi AC, Pai AL, Hommel KA, *et al*. Pediatric self-management: a framework for research, practice, and policy. *Pediatrics* 2012;129:e473–85.
22 Guinet-Lacoste A, Charlanes A, Chesnel C, *et al*. Intermittent Catheterization Adherence Scale (ICAS): A new tool for the evaluation of patient adherence with clean intermittent self-catheterization. *Neurourol Urodyn* 2018;37:2753–7.
23 Creswell JW. *A concise introduction to mixed methods research*. Los Angeles, CA: Sage Publications, 2021.
24 Kim H, Sefcik JS, Bradway C. Characteristics of Qualitative Descriptive Studies: A Systematic Review: Qualitative description: Systematic review. *Res Nurs Health* 2017;40:23–42. Available: https://doi.org/10.1002/nur.21768
25 Lincoln YS, Guba EG. *Naturalistic inquiry*. Beverly Hills, CA: Sage Publications, 1985.
26 Thomas DR. A General Inductive Approach for Analyzing Qualitative Evaluation Data. *Am J Eval* 2006;27:237–46.
27 Harris PA, Taylor R, Minor BL, *et al*. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform* 2019;95:S1532-0464(19)30126-1.
28 The R Project for Statistical Computing, Available: https://www.r-project.org/
29 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101.
30 Salmona M, Lieber E, Kaczynski D. *Qualitative and mixed methods data analysis using dedoose: a practical approach for research across the social sciences*. Los Angeles, CA: Sage Publications, 2019.
31 Sandelowski M. What's in a name? Qualitative description revisited. *Res Nurs Health* 2010;33:77–84.