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Title

Face- and content validity of the UFS in-hand manipulation assessment instrument for children in South Africa

ABSTRACT

Introduction: No standardised assessment instrument that covers all the components of in-hand manipulation with evidence of instrument development and psychometric properties appropriate for South African children currently exists. The UFS In-Hand Manipulation Assessment instrument is under development to become a standardised assessment instrument for children in South Africa. This article aims to report on the first -and second stages of the face- and content validity process of the UFS in-hand manipulation assessment instrument.

Method: A quantitative descriptive study design with a convenient sampling method was used. Participants provided their expert judgement by completing an EvaSys online questionnaire.

Results: Fifty-five (n=55) occupational therapists registered with the HPCSA participated. The participants agreed (above 80% rate) that the instrument's content is relevant and representative to assess all components (separately and as a whole) of in-hand manipulation, the instrument sets out to measure. 'Participants' comments and practical recommendations will form an important knowledge base for the instrument developers to utilise in the third stage of content validity, namely revising and refinement.

Conclusion: Results indicated face- and content validity of the UFS in-hand manipulation assessment instrument, which supports further development and psychometric testing of the UFS in-hand manipulation assessment instrument for children in South Africa.

Keywords: in-hand manipulation; assessment instruments; instrument development; psychometric properties

INTRODUCTION

Key considerations in choosing a sound assessment instrument are grounded on instrument evaluation frameworks, instrument development theories, and clinical research methodologies[1–6]. Cognisance of these considerations is pivotal during any decision-making process for potential assessment instruments in clinical practice or research[1–6]. But, often, the lack of sound assessment instruments may lead to the refinement of existing instruments or the development of new instruments.

However, developing valid and reliable instruments can be a costly, time-consuming, and iterative process[7,8]. Instrument development is a scientific process that involves many systematic steps. Although various authors provide guidelines, there is no simple, predetermined, step-by-step guide to plan, develop and validate an instrument. In addition, complex statistical analysis is often required to determine and establish the psychometric properties of an instrument[7–9]. Therefore, developing a new instrument is a process that can only be justified if there is either no instrument to assess a particular construct or if no sound instruments are availabe.

But how do you know what is available in a field – in this case, in-hand manipulation assessments? A scoping review method of knowledge synthesis is one suitable method to map out the available literature landscape of assessment instruments[11]. A broad overview and critical appraisal of published in-hand manipulation assessment instruments to determine if they do comply with all the requirements of a sound assessment instrument was conducted in a recent scoping review[11]. This scoping review foregrounded that from the eleven available published instrument[12–22] "none had comprehensively completed the instrument development process to the point of standardisation with evaluated psychometric properties" [11:1]. Therefore further refinement of existing instruments or development of new instruments was recommended.

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Another way to identify the need for an assessment is to explore end-users (practitioners) current assessment methods and their preferences for suitable instruments. From a recent South African study, it became clear that paediatric therapists have limited familiarity with published in-hand manipulation instruments, assess in-hand manipulation mainly through informal observations, and voiced their need for a well-developed and scientifically soundinstrument[23].

Two other South-African in-hand manipulation assessment studies describe the in-hand manipulation skills of 353 South African children with anIn-Hand Manipulation (FSU IHM)

Checklist[19,24]. However, this checklist was designed as a data collection instrument without a comprehensive instrument development process and not generalisable to the South African population.

With these studies as background, a formal instrument development process of the UFS In-Hand Manipulation Assessment instrument's development was commenced for children in South Africa. . As a newly developed instrument, an important first step of psychometric testing is to determine if relevant and representative content of the targeted construct has been included in the assessment instrument[25,26]. This article therefore aims to describe the face- and content validity of the UFS In-Hand Manipulation Assessment Instrument for children in South Africa.

LITERATURE REVIEW

Factors for consideration when choosing assessment instruments

The availability of a wide range of assessment instruments is of great value to the profession, cosidering the wide scope of services provided by occupational therapists. However, therapists need to be thoughtful in their choice of instruments to ensure best assessment practices[2]. Available guidelines mostly grounded on instrument evaluation, instrument development theory, and clinical research methodology[1–8] may assist therapist in their selection of instruments.

Before using assessment instruments, therapists could review instruments critically against a set of criteria (as demonstrated in, for example, an evaluation framework)[2,27]. The five broad categories in Rudman's framework describe clinical utility (including aspects such as availability to purchase, time to administer), standardisation (i.e., examiners procedure and scoring manual), purpose, psychometric properties, and patient's perspective[2].

Furthermore, therapists could also review the instrument to determine whether a systematic instrument development process was followed and recorded for an instrument to be considered scientifically sound[1,4,5]. Different authors have recommended a sequence of steps that should go into the development of instruments[2,3,5,8].

After the instrument development phase, instruments should be field-tested (pilot tested), and evidence about the psychometric properties should be researched[3,5]. The nature of the psychometric evaluations depends on the kind of assessment instrument but generally include

reliability (inter-rater, intra-rater, test-retest and internal consistency), validity (face, content, construct, criterion, concurrent, and predictive validity), and responsiveness (longitudinal validity)[1,5,6,28,29].

Lastly, a very important continuous consideration when choosing an assessment instrument is whether the instrument's social, cultural, religious, gender, and contextual relevance has been considered[30,31]. Guidelines when developing/adapting a test for use across cultural and linguistic groups are available for instrument developers[32–34].

Thus, cognisance of available guiding factors is pivotal during any critical evaluation process of potential assessment instruments to be purchased and used in clinical practice, research, and development and refinement of instruments.

The UFS In-Hand Manipulation Assessment instrument

For instrument development, different sequential stages are recommended, but there is no one standard process to follow. "Instrument development is an ongoing process that arguably, has no clear endpoint"[5:174] and often instrument development is not a linear process but an iterative process of refinement. During the planning and development of the UFS In-Hand Manipulation Assessment Instrument, a combination of different authors' processess was considered[5,7,8,10,25,26,35]. The instrument development process was also predicated on the researchers' clinical experience, review of literature, and review of existing instruments.

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Identifying the need for the instrument

Before the development of this instrument commenced, the need for an in-hand manipulation assessment instrument was identified. The need for an instrument was identified through a study that described the current and preferred in-hand manipulation assessment methods used by occupational therapists in South Africa. This study signified therapists' need for a standardised, norm-referenced, contextually relevant in-hand manipulation instrument for paediatric practices in South Africa[23].

Additionally, the researchers used a recently published scoping review on existing in-hand manipulation instruments to appraise and compare existing instruments[11]. At the time of the scoping review, none of the eleven instruments had comprehensively completed the instrument development process to the point of standardisation with evaluated psychometric properties[11]. The

conclusion and recommendations from this scoping review justified the development of a new instrument that differs from the existing instruments for the South African paediatric population.

Identifying the type, purpose, approach of the instrument

Assessment instruments can be classified in numerous ways, and terminology is used incoherently in literature[1]. But, during the development of this instrument, the *type* of instrument, the *purpose*, and the *approach* followed were used as guided by literature. The *type* of instrument was identified to be a standardised instrument norm-referenced instrument. Standardised assessment refers to an assessment instrument designed to measure a child's abilities with the norm for their age group or a criterion and has uniform procedures for administration and scoring. These assessments have undergone a process of development to ensure data are collected systematically and accurately and have psychometric rigidity[36,37]. Standardised instruments are further divided into norm - and criterion-referenced instruments[31]. "Norm-references instruments are used to discriminate between participants, predict the results of some tests, or evaluate change over time"[6:3]. This norm-referenced instrument is designed to portray differences among children's in-hand manipulation skills along a continuum of values and indicate, for example: how does the average five-year-old child score on in-hand manipulation skills[1,6]?

Depending on the *purpose* of the evaluation, literature refers to descriptive, predictive, and evaluative instruments. This descriptive instrument will use criteria to describe a child's status (in-hand manipulation skills) at one moment in time (and may involve comparing results of the children with group norms). Whereas predictive instruments classify individuals and are used to predict a specific outcome, evaluative instruments use criteria/items to measure a change in an individual/group over time[2,27].

The specific *approach* of an instrument is also an important considering factor. One of these approaches is the naturalistic observation approach that "attempts to capture a child's real-life skill performance allowing an objective assessment in common childhood activities"[38:117]. Two other approaches are occupation-based versus component-based assessments. Where the occupation-based assessment permits the therapist to focus the evaluation of children's occupational performance on their meaningful occupations in relevant environments, the component-based assessment allows the therapist to focus on the evaluation of a child's occupational performance components (client factors) to identify possible underlying factors that can potentially cause occupational performance difficulty (also refer to concept clarifications)[39]. In developing this instrument, the researchers considered both approaches, but a predominantly component-based

assessment with elements of occupation-based activities was compiled[40]. Although the wording "lets play" is used in the administration guidelines, the children do not engage in occupation-based play activities per se as defined within the occupational therapy domain[41]. Children are clearly instructed on what to do in the assessment, and the activities are not "freely chosen, intrinsically motivated, internally controlled"[41:71]. Play activities from an OT perspective are more multidimensional and complex than what this instrument's activities can allow for.

As a result, the UFS In-Hand Manipulation Assessment instrument was developed to become a standardised, norm-referenced, descriptive, component-based assessment instrument to assess the in-hand manipulations skills of children in South Africa.

Theoretical foundation and construct identification

The following stage in the development process was to articulate the construct and all fundamental aspects of the construct. The construct or domain refers to the aspect that will be assessed. The developer should identify, define, and delineate the relevant construct and sub-constructs (dimensions of the domain) to be included in the instrument. A well-defined construct will provide the foundational knowledge and set the boundaries of the construct/s to be included in the assessment instrument[7,10].

Theliterature provided conceptual definitions of the construct and subconstructs of in-hand manipulation that served as a conceptual framework. The conceptualisation of the term in-hand manipulation was developed from the foundational work of researchers in the field such as Elliot and Connolly (1984)[42], Exner (1986, 1990,2006)[43–45], and Pont, Wallen, and Bundy (2009)[46]. The Modified Classification System of In-hand Manipulation was the latest contribution in in-hand manipulation[46]. The establishment of this classification system assisted researchers in this field to determine the construct (and subconstructs) *a priori*, as supposed to *posteriori* (if none existed)[7]. As a result, the UFS In-Hand Manipulation Assessment instrument is based on the six distinct components of this classification: (i) finger-to-palm translation to achieve stabilisation; (ii) palm-to-finger translation; (iii) simple shift; (iv) complex shift; (v) simple rotation; and (vi) complex rotation, to ensure that all in-hand manipulation components are included[46].

Item generation

The next stage was to generate appropriate items for each component of in-hand manipulation. This stage is also called "item pool generation" [7,8,21]. The item generation started with a literature study and appraising of previously existing in-hand manipulation assessment

instruments[11,16,19,21,24,47], using the 'researchers' clinical experience, and a formalised expert input from clinicians in South Africa[23] to avoid construct-irrelevance[25]. The target population for the assessment instrument was considered by identifying and/or generating contextual, relevant items, familiar objects in everyday tasks, low cost, and easily available to the instrument developers and therapist to replace[21]. Specific needs from clinicians in South Africa were also considered[23].

A final version of fourteen items was pooled for the UFS In-Hand Manipulation Assessment instrument (figure 1). Each of the six different domains (sub-constructs) of in-hand manipulation consists of two to four different items to avoid construct under-representation[25]. Items are structured as a short "game", task or activity, for example a pegboard game, unscrewing of a container lid, a money game, a piggy bank activity, a marble game, a dressing game, and a stringing beads activity, a pencil game, fanning cards, nuts and bolts and a key activity. These test items were constructed to assess in-hand manipulation with and some without stabilisation. Hence the two major threats to content validity, namely construct-irrelevance and construct under-representation were considered[25].

Furthermore, a selection criteria were considered in the development of all the items similar to Chien et al.[18]: (1) to be representative of common childhood occupations that require in-hand manipulation; (2) to present specific difficulty and mastery (age-appropriately) to children ages 3–12 year; (3) to be easily instructed and observed while placing minimal demands on language, cognition, and perception; and (4) to have minimal gender or cultural bias[32] for children when performing the tasks.

The administration and scoring system

Generating the administration and scoring system/procedure as a guide to accompany the instrument was part of this stage of the development[8]. The administration guidelines include an administration layout of each test item concerning the activity, in-hand manipulation component, equipment/ material, the layout of equipment, a picture of the layout, the assessor says, the assessor does, practice item, trials, scoring and stop rules (figure2). The scoring guideline consists of a scoring scale, quality of tasks, the speed, control of objects, and compensation methods used (figure3).

To determine the format of the instrument, "the actual mechanism by which information will be gathered and translated into numbers" [5:174] is another important aspect to consider. For this instrument, the therapist conducting a clinical assessment with a child will be the mechanism by

which information will be gathered. During the assessment, the therapist will use the scoring guideline to record the child's scores and afterwards, it will be calculated and translated into numbers. The therapist will follow the prescribed administration and scoring guidelines carefully.

The formulation of a scoring guideline was based on the scale construction of the ACHS[18], the Functional Repertoire of Hand Model[48], the Children's Hand Skills Framework (CHSF)[49], the content of ELOM assessment guide[50], and recommendations from Kruger's study[23], to create a preliminary research version.

Determining psychometric properties of assessment instruments

Rudman[2] states the importance of why an assessment instrument is applicable for what the therapist aims to assess. By developing an instrument evaluation framework, Rudman implies the following is important for selecting an assessment instrument: clinical utility, standardization, purpose, psychometric properties, and client's perspective. Psychometric properties consist of item construction, reliability, validity, and establishing norms[2]. For item construction, the items of an instrument must be equivalent to the test's purpose, and a rationale must be included based on item selection[2]. After item construction, the assessment instrument's validity and reliability need to be established.

Reliability of an instrument is the consistency of the test's results during different time slots or using different respondents from the same population group[2, 52]. If a test is reliable, measurement errors are minor, and the test results will be consistent no matter the rater, subject or time variables. There are three different types of reliability, namely, test-retest, inter-rater and intra-rater[2]. Validity and reliability are important in using assessment instruments for both clinical practice and research, where it is vital to choose the right assessment for the right purpose[1,5,6,28,29,52].

The validity of an instrument is defined by how accurate an assessment instrument measures what it intends to measure[52,53]. According to Maree (2016), there are four different types of validity, namely, face, content, construct, and criterion[52]. Face validity is defined as how an assessment instrument appears to be valid from a test-taker's perspective. Even though it is not always quantifiable[52] it "promotes rapport and acceptance of testing and test results on the part of test takers" [8:169].

Content validity refers to the adequacy with which an instrument covers the complete domain of content it sets out to measure, meaning the content of an in-hand manipulation assessment instrument should be relevant and adequately representative of all in-hand manipulation components (relevant content should be included but irrelevant content should also be excluded). To ensure the content validity of an instrument, the constructs being measured needs to be conceptually defined. Then only can items be selected and constructed to represent the construct adequately[1,52,54]. According to Boateng, apart from content relevance, content representativeness, technical quality is also important[7].

Many authors have recommended methods of content validation called *recomemneded steps*, or *guidelines*, but mostly demonstrates a similar sequence of content validation. For this study a few authors have been considered and followed. Some literature suggests a three-stage process to evaluate the content validity of an instrument: firstly, *a priori* effort (or developmental stage) where the researchers use their clinical experience, review relevant literature and review existing instruments[5,25,26,54,55]. This stage has three steps: domain identification, item generation, and instrument formation (described in 2.2). Secondly, a posteriori effort (judgment-quantification stage) to evaluate the relevance of the instrument's content (each item and the total scale), seeking multiple expert judgement of items constructed, and obtaining perceptions of experts who will have to respond to the assessment instrument (the focus of this article)[8,25,26,53,55]. Thirdly, the revising, reconstructing, refinement stage where the instrument developer can utilise the expert's comments (retained, modified, omitted or added to the instrument under development)[8,55] (described in recommendetaons).

For stage two, numerous methods of quantifying experts' degree of agreement regarding the content relevance of an instrument have been proposed. This could be evaluated by gathering experts' judgement or using statistical measures[25]. Content validity can be established by using a predetermined criterion of acceptability (consensus)[8,54,55]. In developing both an in-hand manipulation assessment instrument[47] and the Asessment of Children's Hand Skills[40] expert groups were used to establish content validity. For this study, an expert group was used to establish the second stage of content validity.

METHODOLOGY

Study design

A quantitative descriptive study design[27], using an electronic EvaSys questionnaire, was conducted to address the research aim. The content validity guidelines recommended by the above literature during initial instrument development were followed for this study[55].

Study population and sampling

Limited literature provides guidelines for selecting and using content experts for instrument development and the number of content experts required to evaluate an instrument[25]. The study population consisted of occupational therapists registered with the Health Professions Council of South Africa (HPCSA) and the Occupational Therapy Association of South Africa (OTASA) working in different contexts. In the timeframe of this research study, the amount of qualified occupational therapists registered with OTASA was 2511. Membership in this association is not compulsory. Convenient sampling was used for this study. All the responses that the researchers received were used in the sample.

Although content validity relies on the subjective judgments of experts, the selection of experts to review and critique the instrument was regulated on the following well-defined inclusion criteria[25]:

- Occupational therapists registered with the HPCSA and OTASA.
- Therapists who have clinical experience in paediatric hand function assessment.
- Therapists who have access to the internet and have an email account.

Measurement instrument

Data were collected through a self-developed online questionnaire via the EvaSys survey system. The questionnaire was developed from literature regarding in-hand manipulation[12,14-21,56,57], instrument development[2,5], psychometric properties (specifically face- and content validity)[5,12,17,18,1,54], and on the in- hand manipulation assessment instrument under development. The questions in the questionnaire were supported with photos taken of children's hands during a simulated assessment with the assessment instrument, as well as definitions of the in-hand manipulation components to guide the participant in completing the questionnaire.

The questions were available in English and divided into five sections:

- background information about the participant
- the instrument as a whole
- the instrument's subtests
- the administration and scoring guideline
- general questions regarding the assessment instrument and recommendations

Pilot testing of the questionnaire

A pilot study was conducted with four occupational therapists who did not meet all the inclusion criteria to participate in the study. Two therapists reviewed a hard copy of the questionnaire and provided feedback on the content, clarity of questions and layout. After their recommendations were worked into the questionnaire with all the related photos, it was converted onto the *EvaSys* survey system. Another two therapists reviewed the electronic questionnaire on the *EvaSys* survey system and provided feedback regarding the layout of the questionnaire with the photos, the technical aspects of answering on the *EvaSys* survey system, the duration and ease of completing the questionnaire online. After the pilot study, final amendments were made, and the questionnaire was uploaded onto the *EvaSys* survey system. The pilot study data were not used for data analysis.

Data collection procedures

Arrangements were made with the administrator of OTASA, who distributed the emails to their registered members with the necessary information regarding the study and access to the questionnaire using their electronic database. A link to *EvaSys* with the information regarding the study and access to the questionnaire was made available online for one month, where the willing occupational therapists had access to the questionnaire and completed it within their own time. Occupational therapists received a reminder email after two weeks. At the end of the questionnaire completion period, the researchers exported all the questionnaires from the *EvaSys* survey system to Microsoft Excel and stored it safely on an external device. The Excel file was sent to the Department of Biostatistics at the University of the Free State to be analysed.

Data analysis

Descriptive statistics namely, frequencies and percentages for categorical data, andpercentiles for numerical datawere calculated.

Ethical considerations

Ethical approval for this study was obtained from the Health Sciences Research Ethics Committee of the University of the Free State (Reference UFS-HSD2019/0224/2304). The participants were informed about the study through an information letter, and by completing the questionnaire, the participants automatically gave informed consent. Participants that did not meet the inclusion criteria did not have access to complete the questionnaire. All personal information received from the pilot and the main study was kept confidential throughout the study.

RESULTS AND DISCUSSION

Demographic profile

The demographic profile of the participants' age, experience, and practice setting was similar to other online survey studies[23] a displayed in Table I.

The participants mainly made use of the following informal ways to assess in-hand manipulation: observation (n=36, 65.5%), drawing, writing, colouring (n=7, 12.7%) and activities of daily living (n=6, 10.9%). The participants made use of the following standardised assessment instruments: the Movement Assessment Battery for Children Second Edition (Movement ABC-2) (n=3, 5.5%), the Miller Functional Assessment and Participation Scales (M-FUN) (n=3, 5.5%), and the Sensory Integration and Praxis Tests (SIPT) (n=2, 3.6%). In the "other" response section, standardised instruments such as the Bruininks-Oseretsky Test of Motor Proficiency Second Edition (BOT™-2), the Bayley Scales of Infant and Toddler Development Third Edition (Bayley®-III), self-developed informal hand function checklists, and the Purdue pegboard tests were listed. Congruent with literature[23], limited familiarity with published in-hand manipulation instruments were demonstrated. Participants rely on observation, activities of daily living or standardised developmental assessment instruments.

Insert Table I here

Concept clarification of in-hand manipulation

The second section in the questionnaire dealt with questions regarding the concept clarification of the in-hand manipulation. Most of the participants (n=51, 92.7%) regarded that the concept clarification section assisted them in recapping and/or understanding the related in-hand manipulation components in the assessment instrument. Participants regarded the concept clarification section to potentially "ensure that all terms are correctly understood by all users" (a participant's words), to be an essential part of the instrumemnt, and when used, might contribute to the reliability of the instrument. This shows that a concept clarification section is necessary, as it provides the same baseline theoretical information for the administrators to perform the assessment.

A clear articulation of the construct and sub-constructs of an assessment instrument is one of the qualities of a well-developed instrument[5]. Definitions to clearly distinguish items from each other is an important part of instrument development and content validation[7]. Such a section is often seen in a well developed assessment instruments.

Face and content validity of the instrument subtests

Insert Table II here

Content validity can be established by using a predetermined criterion of acceptability (consensus)[25,54,58]. For this study, consensus to establish the face- and content validity was defined as an agreement with a question by at least 44 (80%) of the participants. The questions regarding the face and content validity of the subtests reflected a positive response of above 80% (n=44).

As seen in Table II, **finger-to-palm translation** had a 100% (n=55) agreement for face validity. All the questions relating to the content validity had an agreement between 96 (n=53) and 98% (n=54). Results regarding palm-to-finger translation had a 100% (n=55) agreement for face validity, and questions relating to the content validity, had an agreement between 96% (n=53) and 100% (n=55). Participants remarked that finger-to-palm translation is assessed with a variety (three) items, each with different objects (money coins, marbles, and dowels) and allows the manipulation of different shapes, sizes, and textures. With this variety of finger movements and levels of difficulty required from the child, content under-representative is prevented[25,53].

Regarding the marble game, the suggestion was to include more "purpose" to this task by asking the children to put the marbles on a specific picture printed on the towel. Some participants expressed their concern about using marbles with young children that might swallow them. However, general safety measures will be incorporated in the guidelines for all test items to avoid any choking hazards.

For the dowels in the pegboard game, one participant suggested that the publisher/fabricator of the instrument must ensure that the dowels are smooth and fit well into the pegboard. Different opinions were given about whether the thickness of the dowels will influence the required level of in-hand manipulation and if different levels of accuracy will be seen in age groups. However, the pegboard game's dimensions and dowels were based on recommendations from similar

instruments[17,19,24,59]. The board (100 x 100 x 20 mm), with nine holes (15 x 7 mm, 32 mm apart), and the dowels (32 x 7 mm)".

Regarding the use of real five-rand money coins in the piggy bank activity, a few participants stated that it is good to use everyday objects but were advised to instead use plastic "play" money or buttons. Recommendations for 3D fabrication of play money with similar dimensions that a two Rand coin will be made in accordance with other instruments used in the previous research[12,14,17,19,24].

Simple shift had a 90%(n=50) agreement for face validity, and an agreement between 85 (n=47) and 96% (n=53) for content validity. The results regarding complex shift had a 98% (n=54) agreement for face validity. All questions relating to the content validity had an agreement between 89 (n=49) and 100% (n=55). In terms of the piggy bank activity,, no other recommendations were made apart from using " play" money.

Regarding the dressing game, it was advised that a thicker, durable material be used to make the dressing boards or to use actual clothing. Furthermore, it was recommended only to use one medium-size button as opposed to different-sized buttons.

Concerning the stringing beads on a pipe cleaner activity, it was advised that the guidelines should state how the forearms and writs should be stabilised on the table. If the correct position is assumed, it might ensure an isolated finger shift movement instead of a wrist or whole hand movement when putting the bead in the pipe cleaner. Although small beads were recommended for older children, the same medium size beads will be used for all ages.

For the fanning card game, it was suggested to use high quality cards that are smooth and grade this activity carefully for different ages by using fewer cards for other age groups.

For the key activity, a practical adaptation was recommended to have a step for young children to climb up to reach the door handle. Or to have a devised doorhandle-lock unit with fitting keys as part of the instrument. Different sized keys were recommended for young children, but the same medium-sized keys will be used as with all the other subtests.

A recurring theme from the participants' comments was about the size of the objects used in the instrument. Since the opinion was that the size of objects might require different related hand

function skills and degree of difficulty, the suggestions towards using different sizes for different ages were made. Contrarily, using the same dimensions (constant construct to assess) for items (i.e.marbles, money, buttons) for all age groups will allow the instrument to determine internal domain differentiation between different groups and provide different age norms during the standardisation of the instrument[60].

A paucity in the literature that relates object size and in-hand manipulation is evident. Evidence that can be considered during the refinement of this instrument relates to the perceived size of an object and how it is seen in terms of the actions that the object affords[61]. The grasp ability and object size are specific to objects within the apparent grasp ability of the hand[61]. Hand dominance and age might also play a role in how children perceive graspable objects[61]. However, the object's size is only one aspect that reflects the manipulation requirements encountered in daily life activities[62]. All aspects of the object's geometric properties (size, shape, and texture) and the material properties (rough, smooth, slippery, sticky, compliant), and intended need to be considered[63]. Electromyography (EMG) signal information gathered before the hand is in contact with an object shows that shape, size and surface properties (like pre-shaping the hand for grasping a soft toy) have more impact on the muscular system than the actual weight of the object to be grasped[63].

Simple rotation had a 94% (n=52) agreement for face validity, with an agreement between 81% (n=45) and 100% (n=55) for content validity. For complex rotation face validity had a 100% (n=55) agreement and an agreement between 94% (n=52) and 100% (n=55) for the content validity.

Regarding the unscrewing container lid activity, the money rotation in a lid activity, the money rotation on fingertips, and the peg rotation activity, no comments or recommendations for adapting the item were made. In terms of the nut and bolt activity, it was stated that "play" nuts and bolts can also be used. This can be manufactured through 3D printing. Careful attention to possible compensation methods such as a child releasing and regrasp and using wrist movements rather than in-hand manipulation was recommended.

For the money flipping game, replacing the laminated cardboard with a piece of fabric or the small towel was suggested. This may prevent the coins from slipping while flipping them. Easier wording for the instructions in the guidelines was also proposed. Regarding the pencil flipping game, it was advised to consider the pencil grip development of younger children (3/4-year-olds) and preferably include different pencil sizes.

General comments were made that the items are culturally relevant, functional, representative of daily childhood activities, use everyday objects, appropriate for children of different ages, and incorporate different levels of difficulty in items (for other age groups). Although the instrument was not intended to assess children's participation during naturalistic, real-life context[30], it does have elements of real-life in-hand manipulation activities. The findings support the literature[18] that was considered during the instrument development phase.

Content validity was verified by participants' agreement (expert therapists) of the adequacy with which the instrument assesses the separate components of in-hand manipulation. Although the target population (for this instrument children) is recommended for content validation studies[55], they will only be used during future studies if this instrument.

Face- and content validity of the instrument as a whole

Insert Table III here

The same predetermined criterion was used for the instrument as a whole[54] with an agreement of question by at least 44 (80%) participants. A 98.2% (n=54) agreement indicated that the assessment instrument could assess in-hand manipulation of children in South Africa, as shown in Table III. The materials used for the different assessment items were agreed to be appropriate by 94.6% (n=52). Each participant (n=55) stated that the assessment instrument assessed all the components of in-hand manipulation. Most participants (98.2%, n=54), agreed that the assessment instrument was divided into appropriate subtests to assess the different components. According to 94.6% (n=52) of the participants, the activities used in the different assessment items were appropriate. For 90.9% (n=50) of the participants, the instrument had easier and more difficult items to assess various aged children. The instrument's 15-20-minute administration time was agreed to be appropriate by 83.6% (n=46) of the participants. An agreement of 78.2% (n=43) regarding the age appropriateness of the instrument to assess children between 3-12-years was the only aspect that did not achieve an 80% agreement.

Participants provided valuable remarks regarding the appropriateness and grading of the activities to consider in the refinement of the instrument. For example, a participant posed the question: "Can we make it more fun?" In congruence, the assessment of children must be done in an interactive, fun[64] and child-friendly space to ensure that the child will engage optimally. Although

the evaluation process of children is a complex process requiring the therapist to adhere to administration guidelines.

Feedback indicated that the instrument should assess the construct in the least possible time regarding administration time. This depended on the type of assessment (i.e., initial comprehensive assessment or in-depth fine motor specific), age and concerns with/pathology of the child. It was remarked that 15-20 minuteswould be too long for the initial comprehensive assessment of young children, whereas others requested at least 30 minutes per child. According to the eleven in-hand manipulation instruments described in a recent scoping review[11], five to seven minutes was the shortest possible administration time, and twenty-to thirty minutes were the longest administration time. However, these tests all varied in the number of tests items (ranging from three – to fifty-five items). Therefore, considering that this instrument consists of 14 items (including trial items), it might be more realistic to presume the administration time might be around 20-30 minutes.

Further recommendations included: the downgrading of some items and instructions for children younger than 5, the current age interval of 3-12 years is changed to 5-12 years, and structuring the scoring guideline to allow for age differentiation[11]. Contrarily, eight of the 11 instruments described in the above-mentioned scoping review include children under five years into their age range. Therefore, it is recommended that the age range not be changed at this stage but be established only after field testing (establishing construct validity) of the UFS in-hand manipulation assessment instrument were done and item difficulty levels displayed[9].

Conclusively, face and content validity were established for the instrument as a whole, with most questions posed reaching an agreement of above 80%.

Administration guideline

It was evident that the administration and scoring guideline is appropriate for this specific assessment instrument and would assist with the execution of each item. All participants (n=55) agreed that the administrator's material and/or equipment for each assessment item is clear. According to 94.6% (n=52) participants, the administration guideline's wording and layout pictures are appropriate and clear to direct administration of the instrument. Future recommendations were to shorten the instructions for the children, reconsider using words like "palm" "flip over", making the instructions of the therapist bold/in another colour, and language editing. According to the literature, the instrument should be reviewed to prove technical quality (i.e., format, printed layout,

grammar, wording, layout) in content validity[6]. The wording of the instructions should be carefully, clearly, and concisely constructed[55] and appropriate for the child being assessed[6], or else it may contribute to measuring error. It was also suggested from participants and literature to include a background section where the purpose, population, construct being assessed, and development of the instrument can be presented with supporting literature[6]. Further development of this instrument aims to establish cultural fairness and translation of the administration instructions across different ethnolinguistic groups as per steps outlined by the COSMIN and Pena[32,33].

All participants (n=55) and most (89.1%, n=49) participants respectively agreed that the instructions to be demonstrated and the verbal administration instructions were clear and easy to understand. The structuring of the table, chair, and equipment and positioning of the therapist in relation to the child should be clear, and including a picture in the guidelines was proposed. Direct instructions must be given on what hand should be used when and how each hand should be used (i.e., the non-dominant hand holds the button board, while the dominant hand opens and closes buttons)[38]. In general, all visual/practical demonstration and verbal instructions must be administered according to the formal/standard way (what the assessor does and what the assessor says Figure2).

The majority of participants (96.4%, n=53), felt that the practice items allowed for the child were clear and easy to understand for each item and that the stop rules were appropriate. However, a better explanation of what is allowed from the therapist during the practice run is required. For example How much time and how many practice opportunities are allowed? Is it allowed to "teach" the child how to do the task? Can the therapists provide hands-on physical support? Can the therapist demonstrate while giving the verbal instructions? The stop rule section's wording of each item needs to be refined. This will be included accordingly during the refinement of the instrument.

The administration and scoring guidelines can be more specific regarding measuring time (i.e., with a stopwatch or estimated) and if there is a time limit for each item (i.e., stop the item after 2 minutes). They recommended that the administration manual of this instrument should include pictures/graphics to better their understanding regarding these aspects. Clarification on the general handling of children can be included. For example, how to handle children with poor concentration and give appropriate breaks. The inclusion of safety/preventive measures (i.e., don't swallow marbles) and a specific section on possible compensatory methods to "look out for" were suggested for the administration guideline.

Scoring guideline

The majority of participants 96.4% (n=53), considered evidence of a scoring scale for the instrument. The instrument's benefit is that it considers the child's quality of a task, speed[22] to perform tasks, control of objects, and compensatory methods used, consistent with other instruments. The refinement of the scale suggested that a differentiation between the left – and right-hand scores need to be added to the scoring form. In accordance with available IHM instruments described in Kruger's scoping review (2021)[11], most instruments (except one) only assess the dominant hand and discourage the use of the other hand. However, it is argued that this instrument should not allow the assessor the option to assess both hands or only the dominant hand in this instrument (especially for children whose dominance is not established or that is ambidextrous).

After the proposed construct validity testing (first field testing of the instrument), researchers will be able to evaluate the practice item, trials and stop rules of the scoring guide and implement the needed changes to create a more refined scoring guideline. In future, the aim is to convert the assessment and scoring guideline onto an electronic platform/device application system[51]. Such an application takes the assessor through each assessment item step by step (with explicit administration instructions, pictures, a stopwatch on the screen, easy scoring options and immediate conversion of the results)[50]. This will minimise inconsistent rating and assist with more accurate systematic data capturing and standardised administration of the instrument. It will also allow the assessor to take short video clips (with the needed prior permission) to assist with observing and scoring fast/difficult in-hand movements and future monitoring purposes.

General comments regarding the assessment instrument

The last section of the questionnaire contained questions regarding further development of the assessment instrument. All participants (n=55, 100%) indicated the need for a standardised in-hand manipulation assessment instrument, for South African children to guide treatment planning and measure outcomes. Most (96.4%, n=53) participants felt that the instrument should be further developed, that it would be valuable to establish all psychometric properties for this instrument (94.6%, n=52), and nearly all (98.2%, n=54) of the participants agreed that it would be valuable if the standardisation of age norms could be established for the diverse South African paediatric population. Once these norms are available, it will be valuable to include age expectations for each item in the guidelines. These findings are in accordance with previous studies in this field[19,23,24].

Most participants (96.4%; n=53) would like to purchase it when made available and use it in their practice, and 98.2% (n=54). . Participants made suggestions for a prefabricated instrument, with a printed manual, allowing copyright of assessment sheets, to increase the instrument's validity and reliability. One participant also stated that it will "ensure that the research that is done is translated to practice" . Still some participants preferred a self-fabricated (free) instrument, making their own test items but buying the manual. This option will open the assessment process to many variables and hence not be possible for this type of instrument. Although publication of an assessment instrument requires a considerable investment in time, financial resources and expertise if intended for commercial distribution[8], it is intended to develop this into a valid and reliable standardised instrument for obtaining reliable data on a child's in-hand manipulation skills.

Additionally, 81.8% (n=45) agreed that such an in-hand manipulation assessment instrument should form part of a more comprehensive hand function assessment instrument but can also be useful on its own. A more comprehensive assessment uinstrumnent would allow for aspects such as reaching, grasping, manipulating and other fine motor tasks to be assessed[65]. Participants concurred that an instrument would assist with a more accurate assessment of children with fine motor difficulties and better treatment planning, and most (74.6%, n=41) participants did not use or were aware of any specific hand function assessment instruments that have an in-hand manipulation section, in their practice.

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Limitations of the study

The participantsin this study was the expert judge that evaluated this instrument and were independent of the developmental process[7]. However, the response rate was lower than in other online survey studies[23], but still compares well with similar face and content validity studies.

Using a quantitative survey methodology to evaluate the face and content validity in this study provided objective descriptive data. However, using different research methods (i.e., qualitative) and other sources (i.e., children) can augment the future psychometric studies of this instrument.

At the time of the study, the EvaSys survey system could not support video recordings of the children using the assessment instrument. However, the questionnaire provided definitions and photos of all assessment activities as a visual guide to all questions.

The questionnaire was detailed, and although it predominantly consisted of close-ended questions, most questions also had the option to provide opinions suggestions (open-ended). The answers to

the open-ended questions were valuable, detailed, practical, and could be incorporated in the refinement of the instrument during the next stages of its development and psychometric testing.

Although not the aim of the study, some of the questions and feedback from this study provided evidence on the instrument's clinical utility (about applicability and practicality).

Recommendations

Concerning further research in the continuous development of this instrument, the following is recommended:

- Consideration of 'participants' recommendations from this study into the current instrument refinement before field testing.
- Continuous refinement of the instrument, followed by field testing.
- A qualitative content validity study.
- Further psychometric testing
- The translation of the instrument to main South African linguistic groups.
- The refinement and revision of the administration manualand scoring guideline into an online version.
- Development and reproduction of assessment kits.
- Developing of on electronic administration and scoring data capturing system
- The development of an intervention guide to support the assessment.

CONCLUSION

This study provided content validity evidence of the UFS in-hand manipulation instrument's content relevance, content representativeness and technical quality as assessed through expert judgment. The proposed conditions that must be satisfied to claim content validity was met for the first and second stage of the content validity process. The findings of this study provide practical information for the third stage of the content validity process, namely the revising and refinement of this newly developed assessment instrument. It is recommended that reseach continues in the evaluation of psychometric properties, and standardisationinto a norm-referenced test for the clinical assessment of South African children's in-hand manipulation skills, to improve assessment practices and support evidence-based practice in occupational therapy.

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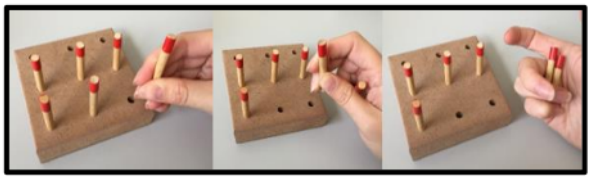
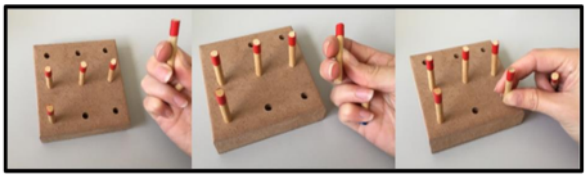
Figure 1 Test items of the UFS In-hand manipulation assessment

Activity/task	Peg-board-game
IHM component:	Finger-to-palm and palm-to-finger translation (with stabilisation)
Equipment/ Material:	Nine-hole Peg-board with nine pegs.
Layout of equipment:	Arrange six pegs into the nine-hole pegboard on a table in front of the child.
Picture:	 
Assessor says	Let's play another peg-board-game. This time I would like you to pick up **two** pegs, just like me and hold it in your palm. Then while holding onto one peg in your hand, put the other one back into the Pegboard. Remember only to use your one hand. Try not to drop a peg.Let's try!
Assessor does	Show the child how to pick up **one** peg with their first, second and third digit, and move it to and store it in their palm with their fourth and fifth digits. Then how to pick up another peg to store in their palm. Then how to move one peg from their palm to the fingertips and place it in the Pegboard while stabilising the other peg with the fourth and fifth digit.
Practice item:	Now it is your turn to try to **pick** up **two** pegs and place them in the board.
Trial 1:	Now let's practice this again. Pick up **two** pegs, hold them in your palm and put it in the pegboard one at a time. Try not to drop any peg and use only your one hand.

Scoring:	1	2	3	Drop	Time	Compensation
Trial 2:	Now let's try to pick up **four** pegs and do the same.					
Scoring:	1	2	3	Drop	Time	Compensation
Stop rule:	Stop if the child cannot perform the practice item and trial 1.					

Figure 2: An example of the administration guideline for Item 3: Pegboard activity

Figure 3: Scoring guideline:

1. Scoring scale:

The assessor needs to document the score according to the child's quality of task, speed, object control, and compensatory methods used.

a) Quality of tasks:

1	Child **cannot** perform the movement/task.
2	Child can perform the movement/task but in an **abnormal manner** and/or with excessive **compensation.**
3	Child **can** perform the movement/task in a normal manner.

b) **Speed:** Time it takes to perform tasks

c) **Control of objects:** If objects are dropped, count items dropped and document them.

d) Compensatory methods to describe may include:

- Fixation of the arm
- Using both hands/arms instead of just the hand being assessed
- Changing hands
- Rotating body
- Stabilising the objects against their body
- Other

Table I. Demographic profile of participants (n=55).

Variables		Median (range)
Age of participants		33 (23–67)
Experience	Years working as an occupational therapist	10.5 (1–40)
		n (%)
Gender	Female	55 (100)
	Male	0
Practice setting (participants could choose more than one answer)	Private practice	40 (72.7)
	Primary school	30 (54.6)
Field of Practice (participants could choose more than one answer)	Paediatrics	45 (81.8)
	Other fields of practice	10 (18.2)
Highest Occupational Therapy qualification	Diploma	1 (1.8)
	Bachelor's	37 (67.3)
	Postgraduate diploma	4 (7.3)
	Master's	9 (16.4)
	Doctorate	2 (3.6)
	Other (i.e. SAISI, NDT courses)	2 (3.6)

Table II: Face- and content validity of the subtest (n=55)

Face and content validity of the subtests							
	Face Validity	Content Validity				Recommendations	
In-hand manipulation component	Does this subtest appear to assess the IHM component? n (%)	Are there different items allocated to assess this IHM component? n (%)	Is there a difference in the difficulty level of the items for this IHM component? n (%)	Are the selected items appropriate to assess children's IHM of this skill? n (%)	Does the subtest assess this IHM component with stabilisation? n (%)	Would you add or remove any items from this subtest of the instrument? n (%)	Would you modify any items from this subtest of the instrument? n (%)
Finger-to-palm	55 (100%)	53 (96.4%)	54 (98.2%)	54 (98.2%)	53 (96.4%)	44 (80%)	41 (74.6%)
Palm-to-finger	55 (100%)	54 (98.2%)	53 (96.4%)	55 (100%)	53 (96.4%)	43 (78.2%)	42 (76.4%)
Simple shift	50 (90.9%)	53 (96.4%)	53 (96.4%)	47 (85.5%)	49 (89.1%)	40 (72.7%)	44 (80%)
Complex shift	54 (98.2%)	55 (100%)	55 (100%)	51 (92.7%)	49 (89.1%)	49 (89.1%)	51 (92.7%)
Simple rotation	52 (94.6%)	54 (98.2%)	55 (100%)	51 (92.7%)	45 (81.8%)	40 (72.7%)	46 (83.6%)
Complex rotation	55 (100%)	54 (98.2%)	55 (100%)	54 (98.2%)	52 (94.6%)	51 (92.7%)	50 (90.9%)

Table III: Face and content validity of the instrument as a whole

Face- and content validity of the instrument as a whole		
Type of validity	**Questions**	**n (%)**
Face Validity	Do you think the assessment instrument can assess the IHM of children in South Africa?	54 (98.2%)
	Are the materials (i.e., buttons, money coins) used for the different items, appropriate to assess IHM of children?	52 (94.6%)
Content Validity	Does the assessment instrument assess all the components of IHM?	55 (100%)
	Is the assessment instrument divided into the appropriate subtests?	54 (98.2%)
	Are the tasks and/or activities used appropriate to assess IHM of children?	52 (94.6%)
	Does the instrument have easier and more difficult items to allow for the assessment of IHM of various aged children?	50 (90.9%)
	Do you think an administration time of 15-20 minutes will be suitable for children?	46 (83.6%)
	Is the instrument appropriate to assess children between the ages of 3 to 12?	43 (78.2%)

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