Effect of the clinical decision support system on clinical outcomes of delirium in hospitalized older adults: study protocol for a pair-matched, parallel, cluster randomized controlled trial

Jiamin Wang (wangjamin.com@qq.com)  
Beijing University of Chinese Medicine  https://orcid.org/0000-0002-8633-5404

Sen Niu  
Beijing University of Chinese Medicine

Ying Wu  
Capital Medical University

Research Article

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Abstract

**Background:** Prompt recognition of delirium is the first key step in its proper management. Previous study has demonstrated delirium screening using usual paper version assessment tool by nurses had no effect on clinical outcomes. Clinical decision support systems have been demonstrated to improve the adherence and clinical outcomes of patients. Therefore, We developed a clinical decision support system (3D-DST) based on the usual paper version (3-minute diagnostic interview for CAM-defined delirium, 3D-CAM), which was developed for the assessment of delirium in older adults with high usability and accuracy. However, there is no high quality evidence exists on the effectiveness of a 3D-DST in improving outcomes of older adults compare to usual paper version.

**Methods:** A pair-matched, open-label, parallel, cluster randomized controlled trial following the SPIRIT checklist. Older patients aged 65 years or older admitted to four medical wards of a geriatric hospital will be invited to participate in the study. Prior to the study, delirium prevention and treatment interventions will be delivered to nurses in both the intervention and control groups. The nurses in the intervention group will perform routine delirium assessment on the included elderly patients with 3D-DST, while the nurses in the control group will perform daily delirium assessment with usual paper version. Enrolled patients will be assessed twice daily for delirium by a nursing researcher using 3D-DST for clinical outcomes. The primary outcome is delirium duration. The secondary outcomes are delirium severity, incidence, length of stay, in-hospital mortality, adherence to delirium assessment, prevention and treatment of medical staff.

**Discussion:** This study will incorporate the 3D-DST into clinical practice for delirium assessment. If our study will demonstrate that 3D-DST will improve adherence with delirium assessment and clinical outcomes in older patients, it will provide important evidence for the management of delirium in the future.

**Trial registration:** ClinicalTrials.gov, Identifier: ChiCTR1900028403.

**What is already known**

- Delirium screening using usual paper version assessment tool by nurses has no effect on clinical outcomes.
- Clinical decision support systems have been demonstrated to improve the adherence and clinical outcomes of patients.
- There is no high quality evidence exists on the effectiveness of a 3D-DST in improving outcomes of older adults compare to usual paper version.

**What this paper adds**

- A cluster randomized controlled trial will be conducted to evaluate the effect of the 3D-DST on clinical outcomes.
Findings will improve policy and practice for delirium management.

**Introduction**

Delirium is a common neurocognitive syndrome in hospitalized older adults with fluctuating symptoms [1-2]. The incidence of delirium in hospitalized older adults has been reported to be 10%~40% in different settings [3-6]. Delirium during hospitalization will increase the risk of falls, decrease cognitive function, aggravate frailty, and increase mortality in older adults [1,7]. The severity of adverse effects were positively correlated with the severity and duration of delirium [8]. Prompt recognition of delirium is the first key step in its proper management.

Relevant guidelines for the routine assessment and management of delirium have been issued [9-10], several studies have found that delirium assessment combined with multi-component intervention can effectively improve clinical outcomes of patients [11-12]. However, majority of patients is not routinely monitored for delirium, thus guidelines are poorly implemented and hindering timely prevention and management [13]. The possible reasons for the low adherence to delirium assessment are multiple but mainly due to the implementation barriers, such as monitoring instrument is not routinely used, complicated procedure of the evaluation instrument, the long evaluation time required for delirium increases the workload of the nurse, etc [14-16]. A prospective study also demonstrate that routine delirium detection by bedside nurses using usual paper version assessment tool had no effect on clinical outcomes [17].

Clinical decision support systems have been widely used in the medical field and have been demonstrated to improve the adherence and clinical outcomes of patients [18-19]. We have developed a clinical decision support system (3D-DST) based on the 3-minute diagnostic interview for CAM-defined delirium (3D-CAM), which is developed for the assessment of delirium in older adults with high sensitivity and specificity [20]. 3D-DST simplified the evaluation process of the 3D-CAM paper version, the usability of 3D-DST is significantly better than that of paper version when used by nurses, and the assessment time has been shortened by 2.1 min [20]. However, there is no high quality evidence exists on the effectiveness of 3D-DST in improving delirium identification and clinical outcomes of older adults compare to usual paper version.

Therefore, we hypothesize that the use of the 3D-DST will improve the adherence to delirium assessment and management by clinical staff, and then reduce the duration and the severity of delirium.

**Objective**

The primary objective is to determine the impact of routine delirium assessment on delirium duration.

The secondary objectives are to determine the impact of routine delirium assessment on delirium severity, incidence, length of stay, in-hospital mortality, and adherence to delirium assessment, prevention and treatment.
Methods

Reporting guideline

Following the defining standard protocol items for clinical trials (SPIRIT 2013) [21]. SPIRIT Checklist is included as Additional file 1 and the SPIRIT Figure is shown in Fig. 1.

Design and setting

This study is a pair-matched, open-label, parallel, cluster randomized controlled trial with 1:1 allocation ratio. Cluster randomization minimizes contamination between groups and accounts for intraclass correlation [22]. Four medical wards (two respiratory and two neurology wards) of a geriatric hospital in China will be invited to participate in the study. The neurology ward and the respiratory ward receive approximately 20 and 40 older adults per month, respectively. This study was registered on ClinicalTrials.gov (registration number: ChiCTR1900028403).

Participants

The participants are older patients continuously admitted to four general medical wards. Patients should be: 1) age \( \geq 65 \) years old, 2) able to communicate effectively in Mandarin, 3) stay in hospital longer than two days. Exclusion criteria are: 1) severe hearing or visual impairment, 2) refuse to participate in this study, 3) continuous coma during the study period, 4) severe dementia which is defined as a diagnosis documented in the medical record because such patients cannot be assessed for delirium. 5) participate in other delirium-related studies. This study was approved by the ethics committee of the Capital Medical University and the study hospital. Patients who meet the inclusion criteria will be informed about the study protocol and the written informed consent will be obtained from the older participant or their legal representatives. Three supervisors will monitor the accuracy and feasibility of the research process once a year.

Instruments for delirium assessment

3D-CAM paper version

A total of 22 items and four features are included in the 3D-CAM assessment. Four features are acute change and fluctuation of mental status (feature one), inattention (feature two), disorganized thinking (feature three), and altered level of consciousness (feature four) [23]. Delirium is positive if both feature one and feature two are present with either feature three or feature four. The 3D-CAM has been translated into Chinese [24]. Previous evidence has shown acceptable sensitivity and specificity of 3D-CAM for routine delirium assessment when used by nursing researchers [24].

3D-DST

Based on the paper version, 3D-DST was developed based on Android-compatible smartphones through three steps, including: analysis of problems in the use of the 3D-CAM, design of the 3D-DST (evaluation
process analysis and optimization [Figure 2], and user interface design), architecture and development of
3D-DST [25]. Optimized evaluation logic flowchart of the 3D-CAM application was shown in Figure 2. A
multidisciplinary team that included experts with rich experience in delirium assessment, bedside nurses,
nursing researchers, software engineers and user interface designer were formulated in developing 3D-
DST. Three assessment modules (inquiry assessment, observation assessment and selective
assessment), 9 assessment interfaces with built-in reminders to guide nurses to complete the
assessment, and 16 result interfaces were included in the final 3D-DST version (Figure 3). 3D-DST solved
the problems of the 3D-CAM when used by bedside nurses, including human error, incorrect
understanding of the project and incomplete nursing records. Our previous research had shown that 3D-
DST had good usability, reduced human error and saved evaluation time compared to the paper version
(2.3min vs. 4.4min) when used by bedside nurses [25].

CAM-S

Inouye et al. has developed a delirium severity scoring system (CAM-S) [26]. CAM-S can only be used to
assess the severity of delirium and cannot be used to diagnose delirium. The simple version of CAM-S
includes the following items: acute episodes or symptom fluctuations, impaired attention, incoherent
thinking, changes in consciousness. The results show that the overall agreement of the CAM-S scale was
97%. The score range is 0 to 7 (0 = normal, 1 = mild delirium, 2 = moderate delirium, and 3-7 = severe
delirium [26]. The CAM-S has been translated into Chinese with high reliability and validity and can be
used as an effective tool to evaluate the severity of delirium [27].

Cluster Randomization and Blinding

Before randomisation, the wards participated in the study will be pair matched according to specialty.
Within each of two pairs, wards will be randomly assigned (1:1) to the intervention or control group using
random numbers generated by the computer, it indicates that each group will contain one neurology ward
and one respiratory ward. The medical staff who will be involved in the study only know the protocol of
their own ward, but not be aware of the protocol of other wards and the hypothesis of the study. Due to
the allocation sequence generating, enroll participants, assign participants, data and outcome collection
will be done by the nursing researcher, therefore the protocol will not be blinded to the nursing researcher.
However, the nursing researcher and the bedside nurse will be unaware of each other's assessment
results of delirium.

Sample size

The primary outcome is delirium duration, we expect that delirium duration of the intervention group will
be 1 day shorter than that of the control group, with standard deviation of 1.8 [28], α of 0.05 and
intraclass correlation coefficient of 0.00001. Our study will be estimated to provide more than 80% power,
at least 5 delirium-positive patients in each group (ward) and a total of 20 delirium-positive patients will
be needed. According to previous study, the incidence of delirium is approximately 10% with an estimated
10% of patients drop out during the study, thus at least 202 elderly patients will be needed. Patients will
be given a detailed explanation of the benefits they will receive from participating in the study to reach target sample size.

**Intervention and implementation**

The intervention include assessment, prevention and treatment of delirium implemented by nurses and clinicians (Figure 4).

1. Delirium assessment

Prior to the study, bedside nurses of the control group and the intervention group will be trained respectively. The nurses in the intervention group will perform routine delirium assessment on the included elderly patients with 3D-DST, while the nurses in the control group performed daily delirium assessment with 3D-CAM paper version. The training will include the concept of delirium, clinical manifestations, the training manual of the 3D-DST or 3D-CAM, and the training will last for 30 minutes. Due to the characteristic of fluctuating of delirium, enrolled patients will be evaluated for delirium twice a day by bedside nurses during the forenoon and night.

2. Delirium prevention and treatment

Prior to the study, our team summarize prevention and treatment interventions according to the NICE (National Institute for Health and Clinical Excellence) guidance and expert consensus in elderly patients with postoperative delirium by Chinese and American experts [9,10,29]. Based on the clinical situation and discussion with geriatric experts in participating hospitals, the final version of delirium prevention and treatment interventions are determined. The researcher deliver the paper version of interventions to the head nurses in both the intervention and control groups. The Intervention details are as follows (Table 1):

A. Prevention: monitoring and management of hypoxemia, early mobility and/or physical rehabilitation, early mobility and/or physical rehabilitation, pain assessment and management.

B. Treatment: identify and manage the possible underlying cause, pharmacologic treatments, information and support, and interventions for people in whom delirium does not resolve.

Table 1. Interventions for delirium prevention and treatment.
<table>
<thead>
<tr>
<th>Intervention</th>
<th>Details</th>
</tr>
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<tbody>
<tr>
<td>Monitoring and management of hypoxemia</td>
<td>Assess for hypoxia and optimise oxygen saturation if necessary.</td>
</tr>
<tr>
<td>Early mobility and/or physical rehabilitation</td>
<td>Encourage the person to mobilise soon after surgery, walk (provide walking aids if needed-these should be accessible at all times), encourage the person to carry out active range of motion exercises, even if unable to walk, the intervention of rehabilitation department.</td>
</tr>
<tr>
<td>Medication reductions</td>
<td>Reduce the types of drugs you use, avoid medications that induce delirium, use alternative therapies or consult a psychiatrist to adjust dosage (anticholinergic drug, anticonvulsant drug, tricyclic antidepressant, antihistamine drug, antiparkinson drug, antipsychotic drug, benzodiazepines, H2 receptor antagonists, non-benzodiazepine, opioid analgesics).</td>
</tr>
<tr>
<td>Pain assessment and management</td>
<td>Optimize postoperative pain control, starting and reviewing appropriate pain management in any person in whom pain is identified or suspected. Preferably with nonopioid pain medications to minimize pain in older adults to prevent delirium.</td>
</tr>
<tr>
<td>In people diagnosed with delirium, a medical evaluation should be performed to identify and manage underlying contributors to delirium.</td>
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<tr>
<td>Pharmacologic treatments</td>
<td>The prescribing practitioner may use antipsychotics at the lowest effective dose for the shortest possible duration to treat patients who are severely agitated or distressed, and are threatening substantial harm to self and/or others.</td>
</tr>
<tr>
<td>1. Hyperactive delirium: the use of antipsychotics (e.g., haloperidol, risperidone, olanzapine, quetiapine, or ziprasidone) at the lowest effective dose for the shortest possible duration may be considered to treat delirious patients who are severely agitated or distressed or who are threatening substantial harm to self and/or others. Cholinesterase inhibitors should not be newly prescribed to prevent or treat postoperative delirium. Benzodiazepines should not be used as first-line treatment of agitation associated with delirium. The principles of drug treatment are as follows:</td>
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<tr>
<td>2. Monotherapy is better than combination drug therapy.</td>
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<tr>
<td>3. Start at the lowest clinically appropriate dose and titrate cautiously according to symptoms.</td>
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<td>4. Select drugs with low anticholinergic activity.</td>
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<td>5. Stop medication immediately.</td>
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<tr>
<td>6. Continued application of nonpharmacologic intervention, identify and manage the possible underlying cause(s).</td>
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<tr>
<td>2. Hypoactive delirium: antipsychotics and benzodiazepines should be avoided for treatment of hypoactive delirium.</td>
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</table>
3. Mixed delirium: when hyperactive delirium occurs, treated according to the treatment method of hyperactive delirium. When hypoactive delirium occurs, treated according to the treatment method of hypoactive delirium.

<table>
<thead>
<tr>
<th>Information and support</th>
<th>Offer information to people who are at risk of delirium or who have delirium, and their family and/or carers. Inform them that delirium is common and usually temporary. Describe people’s experience of delirium. Encourage people at risk and their families and/or carers to tell their healthcare team about any sudden changes or fluctuations in behaviour. Encourage the person who has had delirium to share their experience of delirium with the healthcare professional during recovery.</th>
</tr>
</thead>
<tbody>
<tr>
<td>For people in whom delirium does not resolve</td>
<td>Re-evaluate for underlying causes. Follow up and assess for possible dementia.</td>
</tr>
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</table>

**Adherence/termination**

As the adherence of medical staff in implementing the intervention is one of the outcomes of this study, the researchers will not intervene on the adherence of medical staff. If participants choose to withdraw, or transfer out of the ward, die or discharge, they will stop receiving the intervention. If the patient fail to complete the evaluation during the evaluation period, the reason will be recorded.

**Study outcomes**

Delirium positive is defined as the occurrence of delirium assessed by a nursing researcher using the 3D-DST. Enrolled patients will be assessed twice daily for delirium by a nursing researcher using 3D-DST for the same time period as the nurses in the wards. Delirium duration, delirium severity, incidence of delirium, length of stay, in-hospital mortality, delirium assessment, delirium prevention and treatment interventions will be recorded by the nursing researcher.

The primary outcome of the study is delirium duration: defined as the number of delirium positive days in older adults between admission and die/transfer from the ward.

Secondary outcomes include six aspects.

1. Severity of delirium, defined as the score of the CAM-S scale evaluated by the nursing researcher.
2. Delirium incidence: defined as the percentage of patients who are delirium-positive assessed by the nursing researcher using 3D-DST account for total number of enrolled patients.
3. Length of stay, defined as the total number of days in hospital from admission to the day of die/transfer.
4. Mortality rate, defined as the percentage of patients who died account for total number of enrolled patients from admission to transfer out of the ward.
5. Adherence rate of nurses’ delirium assessment: defined as the percentage of the number of actual delirium assessments by the nurse account for the total number of desired assessments.
6. Adherence rate of delirium prevention and treatment: defined as the percentage of the total number of preventive and treatment interventions actually implemented by nurses and clinicians account for
the number of theoretically completed interventions.

Data collection

A nursing researcher enroll the elderly patients according to inclusion and exclusion criteria and collect demographic data at admission, including sex, age, ethnicity, education level, marital status, smoking, and drinking. Clinical data include diagnosis of major diseases, visual acuity level, hearing level, cognitive function, physical function, depression, comorbidity. The mini-mental state examination (MMSE) is used to assess cognitive function, the total score is 0-30, the higher the score, the better the cognitive function [30]. Geriatric depression scale (GDS-15) is used to assess depression, the overall score is 0-15, with less than 8 indicating depression [31]. Charlson comorbidity index (CCI) is used to assess comorbidity index, the higher score indicates more underlying diseases of the older people [32]. Modified barthel index (MBI) is used to assess the activities of daily living at admission by the nursing researcher, the higher score indicates better mobility and restraint use during hospitalization will also be recorded [33].

The delirium assessment data will be stored in a smart phone, which has been installed the 3D-DST and the data can be exported. Patients' general and clinical data are collected using questionnaires and the data will be input into SPSS by two researchers and checked for errors. The data is stored by the investigator and is confidential before, during and after the trial. Only the investigators responsible for the outcome collection and supervisors of this study have access to the data according to the protocol.

Prior to the study, a study group is established, all adverse events will be reviewed regularly by the researchers, and a meeting of the researchers will be convened if necessary to assess the risks and benefits of the study. All adverse events will be recorded in detail, properly handled, and followed up until the adverse events are properly resolved, and serious adverse events will be reported to the ethics committee and authorities according to regulations.

Statistical analysis

SPSS 22.0 (SPSS Inc., Chicago, Illinois, USA) will be used for statistical analysis. Multiple imputation will be used to fill in missing data using the R software. P-value of 0.05 will be defined as statistically significant. The continuous data will be tested for normality and homogeneity of variance by "One-Sample Kolmogorov Smirnov Test" and "Homogeneity of Variance Test". Mean and standard deviation (SD) will be used for normally distributed continuous variables, median and interquartile range (IQR) will be used for continuous variables with non-normal distribution. Rank sum test and t-tests will be used for comparing the demographics and clinical characteristics between different groups. Categorical variables will be expressed in frequency and percentage, and Chi-square test or Fisher’s Exact Test will be used for comparing variables between different groups. The effects on clinical outcomes will be analyzed by generalized linear mixed model. Subgroup analysis will be performed to eliminate the effect of confounding factors. Data will be analyzed according to the per protocol principle. The preliminary analysis will be conducted after the start of the study (three months, one year, close out).
Discussion

Routine assessment of delirium is essential for early identification of delirium, including identifying positive patients and their risk factors for delirium, and thus improving clinical outcomes. However, the effectiveness of routine delirium assessment using clinical decision support system on clinical outcomes by bedside nurses has not been rigorously evaluated. In this study, a smartphone based clinical decision support system (3D-DST) will be incorporated into clinical practice, and the effect of the use of 3D-DST on the adherence of nurses’ delirium assessment, adherence of delirium prevention and treatment measures as well as the clinical outcomes of elderly patients will be evaluated through a cluster randomized controlled trial. If our study demonstrate that the use of 3D-DST will improve the adherence to delirium assessment by nurses, improve clinical outcomes of older patients, it may significantly improve the care and management of delirium patients in hospital.

The design is a parallel, cluster randomized controlled trial, which is of higher quality than the results of non-randomized trials and can provide strong evidence for the effectiveness of the implementation protocol. In addition, participating wards will be paired on the specialty and effectively reduce the risk of contamination and bias between study groups.

In recent years, there has been increasing concern among healthcare professionals about delirium, and many guidelines and associated professional organizations has also recommended routine assessment of delirium (preferably each shift) [14]. However, the adherence of nurses using assessment tools for daily delirium assessment is still poor, and delirium assessment has not been incorporated into clinical practice [34]. Therefore, improving adherence with nurses’ routine delirium assessment is critical to change clinical outcomes of patients. Although 3D-CAM has been recognized as an ideal assessment tool for the diagnosis of delirium in older adults, previous studies have demonstrated that human errors and evaluation problems may occur when used by nurses [35]. Therefore, we have developed the 3D-DST on the basis of 3D-CAM, and the results showed that the usability of 3D-DST was significantly higher than that of 3D-CAM. Therefore, this study will be conducted to compare the adherence of delirium assessment using 3D-DST and 3D-CAM when used by nurses, and evaluate its impact on clinical outcomes.

Improving clinical outcomes in elderly patients should be combined with preventive and treatment measures in addition to routine assessment. The preventive and treatment measures will be adopt in this project were summarized based on guidelines and expert recommendations on delirium. The clinical feasible interventions, including pharmacological intervention and non-pharmacological interventions, have been determined through full discussion with Geriatricians and managers of the study hospital. Therefore, the intervention program will be feasible.

Limitations of this study. This study will require the nursing researcher to collect outcomes in all the participating wards, it will not possible for the nursing researcher to keep blinded to the protocol implemented by nurses, so an open-label trial is designed. However, clinical staff will keep blinded to the
results performed by the nursing researcher, thus an open-label design will not affect the results. Although our study will be conducted in only one hospital, the results may have limited generalization, but we believe that the main conclusions of this study will provide an important preliminary research basis for the management of delirium in the future.

**Trial status**

Enrollment is ongoing. Recruitment has began from September 2020 and will be expected to conclude in November 2023. Target enrollment for the study is 202 participants. The trial was registered at ClinicalTrials.gov. Protocol version: 1, 1/9/20.

**Abbreviations**

3D-DST: Clinical decision support system based on the 3-minute diagnostic interview for CAM-defined delirium;

3D-CAM: 3-minute diagnostic interview for CAM-defined delirium;

CAM-S: delirium severity scoring system;


**Declarations**

**Competing interest:** The authors have no conflicts of interest to declare.

**Funding:** This study was supported by the Beijing Municipal Education Commission “Focus on building first-class majors” and Beijing University of Chinese Medicine “New teacher start-up Fund project”. The institution that funded this study was not involved in this study.

**Acknowledgements:** We thank all the clinical departments and the older adults in Beijing Geriatric Hospital for their support of this study.

**Trial registration:** ClinicalTrials.gov, Identifier: ChiCTR1900028402.


**Ethics approval and consent to participate:**

This study was approved by the ethics committee of the Capital Medical University and the study hospital (Number:2019-022). Written informed consent will be obtained from the older participant or their legal representative.

**Availability of data and materials:**
The data that support the findings of this study are available from the corresponding author upon request.

**Ancillary and post-trial care**

Not applicable. No additional care is provided in the trial.

**Dissemination policy**

The results from the study will be published in a peer-reviewed journal. The dataset is available upon request from the corresponding author.

**Consent for publication**

Not applicable.

**Patient or public involvement in the design of the protocol**

Patients are not involved in the design of the study protocol.

**Protocol amendments:**

Any modifications to the protocol may affect the conduct of the study, potential benefit of the participant etc. The modifications will be approved by the ethics committee of the hospital.

**Authors’ contributions:** Jiamin Wang: Conceptualization, Methodology, Funding acquisition. Writing - Original Draft. Sen Niu: Writing - Original Draft. Ying Wu: Conceptualization, Methodology, Writing - Review & Editing, Supervision, Project administration.

**Name and contact information for the trial sponsor**

Beijing Municipal Education Commission "Focus on building first-class majors"

Beijing University of Chinese Medicine “New teacher start-up Fund project” (2022-JYB-XJSJJ-039).

Email: helenywu@vip.163.com.

**References**


Figures
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<th>TIMEPOINT**</th>
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<td>Adherence rate of delirium prevention and treatment</td>
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**Figure 1**

Schedule for enrolment, data collection, assessments, interventions and outcome measures
Figure 2

Evaluation logic flowchart of the 3D-CAM application
Figure 3

Interfaces of the 3D-DST

Figure 4
Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRITChecklist.doc