Online Supplement 3: Screening reference sheets and forms

The following forms and reference sheets are proposed for abstract screening and full-text review. Reference sheets will be extensively piloted, revised as required, and provided to each reviewer to use during screening. Review forms and their associated logic are programmed into DistillerSR, where reviewers assess abstracts or full texts and provide answers to the required questions. Final versions of these materials will be published alongside the final study results.

Acrynyms:
DMO - Digital Mobility Outcome
GaWP - Gait and Walking Parameter
PD – Parkinson's Disease
MS – Multiple Sclerosis
COPD – Chronic Obstructive Pulmonary Disease
PFF – Proximal Femoral Fracture

Reference sheets and forms:

Mobilise-D Scoping Review: Abstract Screening Worksheet

Overview:

- This review will explore the potential of DMOs as clinical trial endpoint measures by identifying, existing evidence on their construct validity, prognostic value, and responsiveness to intervention
- Our four research questions aim to explore the following:
  - RQ1: The differences in GaWPs between target populations and healthy controls
  - RQ2: The relationship between GaWPs and traditional clinical measurements
  - RQ3: The prognostic value of GaWPs
  - RQ4: The use of GaWPs as endpoints in interventional studies

Question 1: Should this paper be included in full-text review? (YES or NO)

	Questions to ask yourself:	YES or Unsure	NO
A	Is the study on an **included population**? *(human studies on Parkinson's, Multiple Sclerosis, COPD, hip fracture)*	Proceed	Discard
B	Does the study assess **gait speed, gait analysis or an included GaWP**? - See reference sheet for list of included GaWPs - Note that some clinical walking tests are included as measures of gait speed (4 meter walk, 10 meter walk, timed 25 foot walk, etc.) and others are not. See reference sheet for details	Proceed	Discard
C	Is the study an **included design**? ○ Examples of Included Designs: ▪ Observational ▪ Case-control (comparing diseased group vs. healthy group) ▪ Cohort ▪ Cross-sectional ▪ Longitudinal ▪ Interventional ○ Excluded Designs: ▪ Case study ▪ Case series (Series of case studies published together) ▪ Review paper	Proceed	Discard
D	Could the study **address one of our research questions?** *(answer YES if any of the following apply)* - **RQ1:** Could the study explore the *differences in DMOs/GaWPs between healthy controls and a target population*? - **RQ2/RQ3:** Could the study *explore a relationship between DMOs/GaWPs and included measurements (RQ2) or outcomes (RQ3) in a target population?* ○ Relationships could be in the form of a correlation, empirical relationship, odds ratio, risk ratio, hazard ratio, prediction model, multivariate analysis, or other association measure - **RQ4:** Does the study appear to be an *interventional study in a target population with a DMO/GaWP as an endpoint*?	Proceed	Discard
E	Are at least **10 individuals** included in the final analysis?	Proceed	Discard

		YES	NO
F	Are there any other **inclusion criteria** that the study **clearly does not meet**?	Discard	Keep

***If you are unsure, please be conservative and include the study in full-text review.*

Mobilise-D Scoping Review Abstract Screen: Reference Sheet

Eligibility Criteria

Criterion	Keep	Discard
Population	PD, MS, Hip Fracture, COPD Mixed populations IF a sub-analysis was conducted	Animal Studies All other human disease areas Mixed populations with no sub-analysis
Study Aim	Studies an included Gait and Walking Parameter according to one of our research questions	Studies with no GaWP and/or which do not address a RQ
Study Design	Any (Case-control, cross sectional, longitudinal, cohort, controlled or uncontrolled trials, protocols (RQ4 only))	Case study, case series Systematic review (or any review)
Technology	Any (sensors, pedometers, stopwatch, speed gaits, instrumented walkways, video, optometric systems, etc.) Specific clinical tests regardless of technology use (see below)	Self-report measures
Setting	Any (home, clinical, lab-based)	NA
Minimum Dataset	10 patients per study arm included in the final analysis	

Gait and Walking Parameters

Spatial Parameters
Step length (mean, variability, asym.)
Stride length (mean, variability)
Step width (mean, variability)

Temporal Parameters
Cadence (mean, variability)
Step time (mean, variability, asymmetry)
Stride time (mean, variability)
Stance time (mean, variability, asymmetry)
Swing time (mean, variability, asymmetry)
Single support time (mean, variability, asym.)
Double support time (mean, variability)

Spatiotemporal Parameters
Gait speed (mean, variability)
Stride speed (mean, variability)

Volume of Walking
Walking time
Step count (excluding pedometer)
Number, length, duration of walking bouts

Included Walking Conditions

Keep:
- Gait analysis or measurement of any included gait parameters
- Dual-task walking, if testing scenario is included
- Some clinical tests, even no technology was used:
  - 4, 5, 10, 30, 50, etc. meter walk tests (or other short distance) – INCLUDE as gait speed
  - Timed 25 Foot Walk (T25FW) - INCLUDE as gait speed
  - 2 Minute Walk Test – INCLUDE as gait speed

Conditionally Keep:
- Timed Up & Go: ONLY INCLUDE instrumented TUG w/ GaWPs measured during walk
- Treadmill Walking:
  - Fixed-Speed Treadmill: INCLUDE any GaWP EXCEPT gait speed
  - Self-Adjusting Speed Treadmill: INCLUDE any GaWP
- 6Minute WT, 12Minute WT, 400m WT, (or other long walking tests):
  - Non-Instrumented Test: EXCLUDE
  - Instrumented test: INCLUDE any GaWP EXCEPT gait speed

Keep if normal gait may have been be analyzed at baseline or if walking condition was used as intervention (generally keep to be conservative):
- Tandem walking or other abnormal walking patterns
- Walking in time to cues (e.g., beats, music, beeping, etc.)
- Purposefully altering gait (e.g., instructions to concentrate on lifting toes)

Research Questions

RQ1: Comparison of GAWPs between a Mobilise-D population and healthy controls
RQ2: Association between a GaWP and a clinical measurement at a single timepoint
RQ3: Prognostic value: Longitudinal association between a GaWP and a clinical measurement or outcome over time
RQ4: Use of GaWPs as endpoints in controlled interventional studies

Population Terms

	Keep	Discard
PD	Parkinson('s) disease, Parkinsonism, idiopathic Parkinson's disease	Atypical parkinsonian syndromes, drug-induced parkinsonism, vascular parkinsonism, progressive supranuclear palsy, multiple system atrophy, corticobasal syndrome, dementia with lewy bodies
MS	Multiple Sclerosis, relapsing-remitting, primary progressive, secondary progressive, progressing-relapsing MS	
PFF	Hip, femoral, intracapsular (subcapital and transcervical), extracapsular (trochanteric, intertrochanteric, pertrochanteric and subtrochanteric) fractures	Non-fracture-related hip arthroplasty or hip replacement
COPD	Chronic obstructive pulmonary disease Chronic obstructive lung disease Chronic respiratory disease (>age of 65)	Pulmonary hypertension, Studies only including asthma patients

- *If the population is mixed, the study must conduct a sub-analysis of one of our populations to be included. If this is unclear from the abstract, be conservative and include.*
- *If you are unsure about the population and the paper meets all other inclusion criteria, include the paper and the disease-specific team will make the determination.*

FAQs

What do I do when…

I am not sure whether a measurement or outcome is included in RQ2/3 criteria
- Some determinations may require disease-specific knowledge. Be conservative and keep the paper.

A testing scenario or type of study is not covered by our eligibility criteria
- If something is not covered by eligibility criteria, raise a question to Ashley and others in the group. We may need to clarify an unforeseen situation.

The abstract does not indicate the technology or method used to measure a GaWP/DMO?
- Include the paper IF it mentions measuring an included gait parameter, gait analysis, or included clinical test of gait speed AND IF it meets all of our other inclusion criteria

Something is completely unclear, and I can't tell whether to include?
- Think about the item that is unclear with regard to the other inclusion criteria. How realistic is it that the criterion is met, given the information that you have?
- Be pragmatic, but inclusive. If all else fails, be conservative and keep the paper.

Polhemus AM, *et al. BMJ Open* 2020; 10:e038704. doi: 10.1136/bmjopen-2020-038704

Mobilise-D Scoping Review: Abstract Screening Worksheet

Legend:
Green text – Describes logic included in form
Prompt: … – Answer triggers another question or form
E – Answer causes study to be excluded
I – Answer causes study to be included

1. Should this paper be included in full-text review?
   Radio answers:
   a. Yes (I, prompt Q3)
   b. No (E, prompt Q2)
   c. Very Unsure (prompt 3rd review by lead reviewer)
   d. Abstract not available/Not in my language (prompt search for full abstract or reviewer fluent in the language of the abstract)

2. Keep paper as background information? (i.e., a relevant review)
   Radio answers:
   a. Yes (Add label "Background")

3. Which MobiliseD disease area is included in this study? (Select all that apply)
   Checkbox answers:
   a. Parkinson's Disease (Send to Parkinson's Disease full-text review group)
   b. Multiple Sclerosis (Send to Multiple Sclerosis full-text review group)
   c. COPD (Send to COPD full-text review group)
   d. Hip Fracture (Send to Hip Fracture full-text review group)

Mobilise-D Scoping Review: Full Text Review Screening Form

Legend:

Green text – Describes logic included in form
Prompt: … – Answer triggers another question
E – Answer causes study to be excluded
Include Study – End of decision tree. Answer causes study to be included

Initial Questions – All abstracts

Question 1: Screening – General Eligibility Criteria (Select all that apply)

- A. Full text is not available (E)
- B. Full text is not in English or one of my fluent languages (Prompt: Q3-Which language?)
- C. The study design was a case study, case series, review, or other non-eligible study type (E)
- D. The article was an interventional **protocol that used a GaWP as an outcome** that otherwise meets the criteria for RQ4 (E)
- E. Only excluded GaWPs were studied (E)
- F. GaWPs were assessed, but **only** during turns, stair climbing, tandem walking, or other excluded walking motions/conditions (E)
- M. Fewer than 10 participants per study arm were included in any relevant analysis (E)
- J. Study population did not meet our inclusion criteria (E)
- K. Part of the study population met our criteria, but a sub-analysis on these participants was not conducted (E)
- N. The study did not address one of our research questions (E)
- None of the above – The study meets general inclusion criteria (Prompt: Q2-Which research question?)

Studies will be excluded unless the language option or 'None of the Above' is selected

Question 2: Which research question(s) did the study address? (Select all that apply)

- Research Question 1 (Prompt: RQ1 screening question)
- Research Question 2 (Prompt: RQ2 screening question)
- Research Question 3 (Prompt: RQ3 screening question)
- Research Question 4 (Prompt: RQ4 screening question)

Question 3: In which language is the full text available?

- German
- Spanish
- Italian
- French
- ** Screeners will be able to add and select options as needed

A request to find a reviewer fluent in the language will be triggered

RQ-specific Screening Questions

Research Question 1 Screening Questions

RQ1 Eligibility criteria - Was the difference in GaWP measurements assessed between healthy controls and a target population?

A. Yes, but fewer than 10 participants per study arm were included a relevant RQ1 analysis (E)

B. The patient population was mixed and a sub-analysis on an included population was not conducted for RQ1 (E)
C. Yes, and all criteria for RQ1 are met – this paper/analysis should be included (Include Study)

Research Question 2 Screening Questions

RQ2 Eligibility Criteria: Was the relationship between a DMO and a clinical measurement assessed in a target population?

A. Yes, but no included/important measurements were studied (E)
B. Yes, but fewer than 10 patients were included in this analysis (E)
C. Population was mixed and a sub-analysis on an included population was not conducted (E)
D. Yes and all eligibility criteria are met – The study should be included (Include Study)

Research Question 3 Screening Questions

RQ3 Eligibility Criteria: Was the relationship between a DMO and a clinical outcome assessed in a target population through a multivariate analysis, prediction model, or machine learning technique?

A. Yes, but no included/important outcomes were studied (E)
B. Study design was not longitudinal (E)
C. The study looked at GaWPs as outcomes rather than variables (E)
D. Patient population was mixed and a sub-analysis on an included population was not conducted for RQ3 (E)
E. Yes and all eligibility criteria are met – The study should be included (Include Study)

Research Question 4 Screening Questions

RQ4 Eligibility Criteria: Was the DMO used as a primary, secondary, or exploratory endpoint in an interventional study?

A. The clinical trial was uncontrolled (E)
B. The reference is only a protocol or study registration, and does not report original results (E)
C. Patient population was mixed and a sub-analysis on an included population was not conducted for RQ4 (E)
D. Fewer than 10 patients per arm were included in the final analysis (E)
E. Yes and all eligibility criteria are met – The study should be included (Include Study)