Consent V1.0.01.10.24

Study Consent

In this trial, consent refers to consent for data collection. It is not possible for patients to opt out from being subjected to the intervention, as the intervention is delivered at the cluster level. Patient participants will be included in this trial under the following modes of consent:
• Opt-out consent for collection of routinely recorded data
• Opt-in consent and assent for non-routinely recorded data, including but not restricted to Quality of Life (EQ5D5L), Disability (WHODAS 2.0) and Return to Work.
• Waiver of informed consent for patients who are unconscious or otherwise unable to provide consent and do not have a legally acceptable representative.
When possible, all patient participants must be approached and provided with information about the study, the option to opt out, and consent for collection of non-routinely recorded data.

Section I: Consent Wavier

Please note that the consent for the collection of the routinely recorded data (in-hospital) will be presumed unless actively declined by the participant/ legally acceptable representative (LAR), using the opt-out form. Information for all forms except for baseline characteristics (marital and work status, education and income), follow-up (Quality of Life (EQ5D5L), Disability (WHODAS 2.0) and Return to Work) will be presumed, unless opted-out.

1. Is this patient included under the waiver of informed consent because the patient is unconscious or otherwise unable to provide consent and do not have a legally acceptable representative?

Section II: Opt in consent for follow up data collection

1. Did the participant/ or legally acceptable representative (LAR) provided consent for collection of non-routinely recorded data

2. Who gave consent for collection of non-routinely recorded data?

3. What is the LAR's relationship with the participant? _____

4. Why was Legally acceptable representative (LAR) approached for consent for collection of non-routinely recorded data?

5. Date when participant or legally acceptable representative (LAR) gave consent for collection of non-routinely recorded data. _____