

Ethical issues of involving people with mental health conditions who lacked capacity to consent in the TaSCS trial

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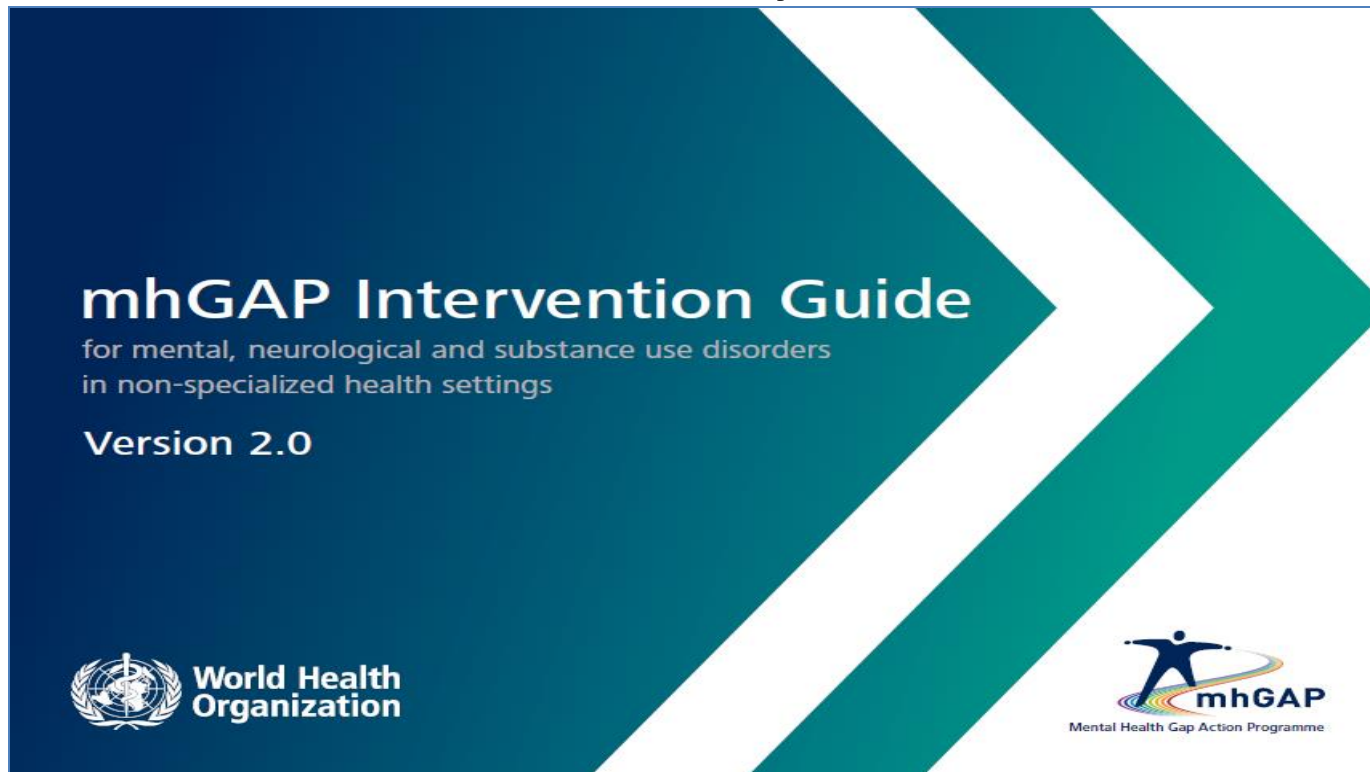
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Background

➤ TaSCS – non-inferiority trial



Background



Background

Lower out-of-pocket costs

Health system efficiency

Better access

Consistent care

Decreased restraint

Background

- Outcomes
 - clinical indicators
 - Functioning
 - stigma
 - quality and safety of care



Ethical issues ...

- Included people who lacked decisional capacity to consent
- ❖ Equity vs autonomy
- ❖ Application to the real world setting



Ethical issues ...

- Concern for wellbeing
 - Procedures to safeguard a person
1. Decisional capacity assessed by psychiatric nurses
 2. When a person was unable to consent permission was sought from their caregiver
 3. Planned to formally reassess capacity in between and at each trial time-point.

Ethical issues ...

4. Out-patient mental health care

- exposure to coercive care beyond the existing risk unlikely

5. Potential risk of receiving inferior care

- DSMB
- Information sheet
- Supervision by psychiatric nurses

6. Advance directive



Recommendations

- Capacity to consent should be assessed well
- Regular examination of decisional capacity
- Identify caregivers who are best
- Involve people with MHCs on research advisory boards



Thank you!!

