ABSTRACT

The protocol describes the intervention provided in both "Kegel exercise and psychosexual counselling", and "usual counselling" for the study titled "Effectiveness of Kegel exercise and psychosexual counselling versus usual counselling for managing erectile dysfunction in incomplete spinal cord injury"

This study was approved by International Review Board (IRB), BHPI, and CRP and the reference number is CRP/BHPI/IRB/06/2020/394.

The study has also been registered to Clinical Trial Registry India (CTRI) and the registration number for this trial is CTRI/2020/07/026395

ATTACHMENTS

- Intervention Protocol.docx

GUIDELINES

The study has also been registered to Clinical Trial Registry India (CTRI) and the registration number for this trial is CTRI/2020/07/026395

MATERIALS

Clinical guidelines of exercise and counselling
SAFETY WARNINGS

Not applicable

ETHICS STATEMENT

This study was approved by International Review Board (IRB), BHPI, and CRP and the reference number is CRP/BHPI/IRB/06/2020/394.

Study process

1. Screening

2. Randomization

3. Baseline assessment

4. Intervention

4.1 Usual counselling

The counselling department follows the PLISSIT MODEL developed by Annon, in 1976.

P = Permission (verbal)
LI = Limited Information
SS = Specific Suggestions
IT = Intensive Therapy

Session -1

Given general information about sex in a group. If some feel interested or motivated then assess the need well as verbal consent. Assist the problems and counseling to the couple about facts regarding sex and problems after SCI. After that arrange a single room focusing
intimation.

Session-2
In this session, find out the outcome of the previous session and find out the leading problem as well as give specific Suggestions/interventions.

Session-3
In this session, find out the outcome of a previous specific intervention. Any type of limitation in sexual activities they try to motivate to use alternatives. In some cases are referred to a doctor for medication.

Session-4
In this session, find out the outcome of the previous intervention by using feedback from the couple and evaluation.

Session-5
Arrange telephone conversations after discharge from the hospital regarding the continuation of sexual activities in the community.

4.2 Psychosexual counselling

<table>
<thead>
<tr>
<th>Contents</th>
<th>Description</th>
<th>Professionals involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1 - Psychosexual Counseling</td>
<td>A counselor is the main educator and tutor for improving and modifying the thoughts, fantasies, desires, beliefs, attitudes, values, behaviors practices, roles and relationships, and interaction of biological, psychological, social, economic, cultural, historical, religious, and spiritual factors.</td>
<td>A clinical psychologist and a Senior Counselor at the spinal cord injury (SCI) unit at Centre for the Rehabilitation of the Paralysed (CRP), Savar, Dhaka, Bangladesh.</td>
</tr>
</tbody>
</table>
Behavioral techniques are mainly used for erectile dysfunction and premature ejaculation. They also have provided some techniques for penile stimulation.

- **Start-stop-** Approach climax and stop to reduce stimulation
- **Pull-out-** Approach climax, vaginal withdrawal to reduce stimulation
- **Pull-out and squeeze -** Approach climax, vaginal withdrawal and squeeze penis tip to reduce stimulation
- **Mind distraction-** A couple or individual thinks about unrelated subjects to reduce stimulation
- **Sex education-** Couple learns ways to reduce stimulation and delay climax
- **Masturbation daily-** for ED as behavior techniques
- **Medication-** for ED
- **Penile Ring-** Local for PE as well as ED
- **Vibrator-** locally and AE behavior techniques
- **Relaxation/ exercise and Psycho-education for – Anxiety/ depression

A clinical psychologist and a Senior Counselor at the spinal cord injury (SCI) unit at Centre for the Rehabilitation of the Paralysed (CRP), Savar, Dhaka, Bangladesh.

A neurologist and a physician working at CRP. One male peer counselor having SCI
### C3 – Peer Counseling

A peer counselor who is a person with a disability is a critical source of information and support. They are the experts on what their bodies experience. They also have experience accessing different resources in the community and can share suggestions on what has or hasn’t worked for themselves or other clients. Persons with disabilities themselves are critical sources of information and support. They are the experts on what their bodies experience. They also have experience accessing different resources in the community and can share suggestions on what has or hasn’t worked for themselves or other clients.

### C4 – Video Show

It is an important method where the patients can learn from the teaching video about sexual life, sexuality, the importance of sex, method of sex. The patient can learn different techniques for penile erection.

Counselling psychologist and a male peer counselor

### 4.3 Kegel exercise

Kegel exercise is a strengthening process that helps to strengthen the pelvic floor muscles. These muscles provide support to the uterus, bladder, small intestine, and rectum. Among pelvic floor muscles, Bulbocavernosus and Ischiocavernosus muscles are directly attached to the basement of the penis which helps to erect the penis and maintain the erection for intercourse.

Kegel exercises can be performed in different positions such as prone lying, crook lying, sitting, and standing. But the patient is in a supine lying position on the bed because the participants were spinal cord lesion patients. Patients were instructed to tighten the pelvic floor muscles like hold and stop the urine & stool passing. The pelvic floor muscle strengthening protocol was followed based on different studies related to erectile dysfunction. The patient was provided an intervention protocol leaflet with a picture, description of treatment based on FITT approach.
<table>
<thead>
<tr>
<th>Variables</th>
<th>Values</th>
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<tbody>
<tr>
<td>Frequency</td>
<td>5 sessions in a week, total of 12 weeks</td>
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<tr>
<td>Intensity</td>
<td>10 rep with 10 sec hold in each pelvic muscle contraction</td>
</tr>
<tr>
<td>Time</td>
<td>3 times/day (self-exercise)</td>
</tr>
<tr>
<td>Type of exercise</td>
<td>Pelvic muscle contraction</td>
</tr>
</tbody>
</table>

4.4 **Doses and Progression:**
Kegel exercise: Intervention for 12 weeks (Exercise 5 sessions/week)
Psycossexual Counselling: Intervention for 12 weeks (2 sessions/week)
Usual Counselling: Intervention for 12 weeks (2 sessions/week)

5 Post Test evaluation

**Evaluation process**

6 Statistical evaluation and result preparation