

TREATMENT DIARY: A TOOL TO OPTIMIZE TREATMENT WITH BOTULINUM TOXIN

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Introduction: Use of a treatment diary can potentially increase patient awareness of problems triggered by spasticity and help patients evaluate their treatment. It may uncover more appropriate treatment goals, and increase patient empowerment and quality of life (QoL). In addition, it may result in a closer collaboration between therapists and physicians. Here, we present the treatment diary, results from a pilot study, and a protocol for the ongoing, randomized, crossover study of the treatment diary.

Methods for pilot study: We enrolled 10 patients. Instruments used for patient evaluation included the WHO-QoL and WHO-5 well-being scores before and after use of the diary and between receipt of 2 botulinum toxin injections. Patients and therapists were asked to fill in a questionnaire on the usefulness of the treatment diary.

Results from pilot study: The diary focuses on problems triggered by spasticity, agreed goals, the patient's self-evaluation of achievement on the Goal Attainment Scale (GAS), which skeletal muscles were injected, therapists' evaluation of the patients' achievements on the GAS, proposals for optimization of treatment, and changing goals. The pilot study showed that by using this tool, patients were more involved in their treatment and it was easier to set personal goals for treatment. All participants who used the diary found the time spent on it worthwhile (Table 1).

Table 1.	Yes	No
Is the diary easy to use?	6 (1)	1 (1)
Are you more involved in the treatment when using the diary?	6	1 (2)
Is it easier to set personal goals for treatment when you use the diary?	6	1 (2)
Is the cooperation about your treatment between the physiotherapist or occupational therapist and your doctor in the hospital improved when you use the diary?	5	2 (2)
Are all parties involved in your treatment better informed about you and your treatment when you use the diary?	6	1 (2)
Is the diary worth applying in relation to the time that you had to spend on it?	7	0 (2)
Allows use of the diary you a higher quality of life?	4	3 (2)

Answers (Yes/No) in numbers from the nine patients who filled in the satisfaction questionnaire related to the Spasticity diary. Two of the patients admitted not having used the diary or completed the diary and have answered "no" to nearly all questions why these are given in brackets.

At present, we are conducting a controlled, multicenter, randomized, crossover study of the use of the treatment diary, which should include input from 96 adult outpatients on stable maintenance treatment with botulinum toxin injections. ClinicalTrials.gov. Protocol Record RH-2017-292.

STUDY DESIGN (Figure 1)

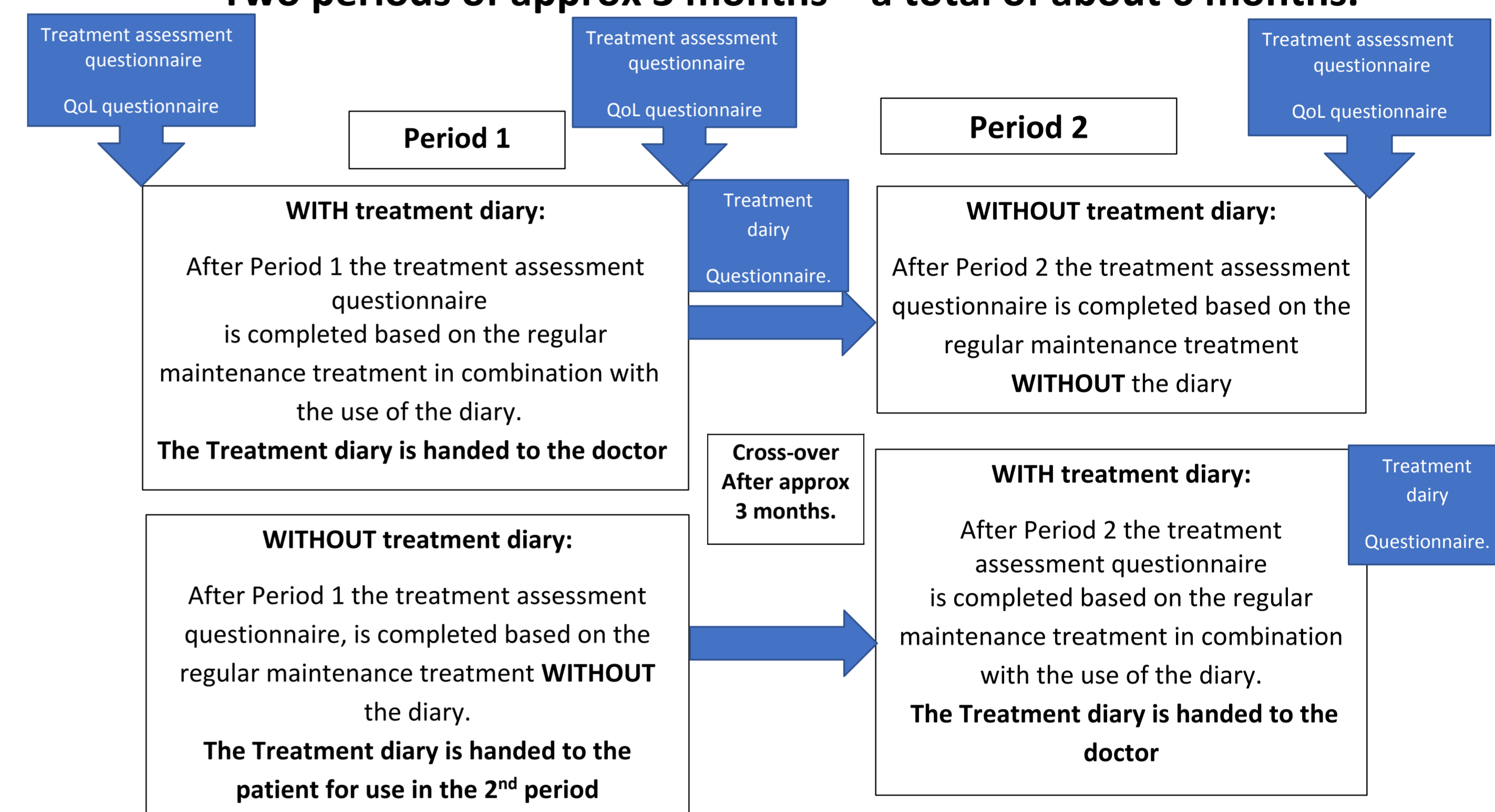
Inclusion criteria:

- Patients with muscle overactivity/spasticity independent of the cause and followed in the Spasticity Clinic of Neurological Department and Clinic for Spinal Cord Injuries, Rigshospitalet, Copenhagen and Spinal Cord Injury Centre of Western Denmark, Viborg Regional Hospital, Denmark
- Patients must have received at least two previous treatment circles, approx. 3 months apart, before inclusion, with good effect in relation to the agreed treatment goals.

Exclusion criteria:

- Patients with planned changes in their oral or therapeutic treatment during the study period.
- Patients with a progressive disease which may influence the treatment effect of the botulinum toxin during the study period, and therefore difficult to set SMART goals (Specific, measurable, attainable, realistic, timely)
- Patients who previously have used the treatment diary in association with botulinum toxin treatment.
- Patients who can't collaborate in goal setting and evaluation due to language or cognitive problems.
- Patients who also are treated with botulinum toxin in the bladder.

Figure 1. **Randomization:** WITH or WITHOUT treatment diary in the first period. Two periods of approx 3 months – a total of about 6 months.



Conclusions:

The presented treatment diary has the potential to increase the patient's awareness of problems triggered by skeletal muscle overactivity and may help the patient to evaluate the treatment better. It may also encourage the patient to be aware of new relevant goals, and will hopefully result in more appropriate treatment goals, increased patient empowerment, and ultimately, lead to higher QoL, although this was not reported in the pilot study. In addition, The diary may lead to a closer collaboration between physiotherapists, occupational therapists, and the physician injecting the botulinum toxin, leading to common goals and optimization of the treatment.

Figure 2 illustrate the treatment diary on the page where the patient can set goals for the treatment and each week evaluate if he/ she is reaching the goal on GAS light. Further the diary contains a page where the physio- and occupational therapist evaluate if the patient is reaching the goals.



The diary is now available in Danish, English, Swedish and Norwegian.

Download at: <https://www.rigshospitalet.dk/>
Search: Spasticitetsklinikken

Reference
 Biering-Sørensen B, Iversen HK, Frederiksen IMS, Vilhelmsen JR, Biering-Sørensen F. Treatment diary for botulinum toxin spasticity treatment: a pilot study. *Int J Rehabil Res.* 2017;40(2):175-184.