Treatment diary for botulinum toxin spasticity treatment: a pilot study

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The aim of this study is to develop a treatment diary for patients receiving spasticity treatment including botulinum toxin injection and physiotherapy and/or occupational therapy. The diary focuses on problems triggered by skeletal muscle overactivity; agreed goals for treatment and the patient's self-evaluation of achievement on the Goal Attainment Scale; which skeletal muscles were injected; physiotherapists' and occupational therapists' evaluation of the patients' achievement of objectives on the Goal Attainment Scale; and proposals for optimization of treatment and changing goals. The evaluation included a satisfaction questionnaire and the WHO-QoL BREF and WHO-5 well-being score. Overall, 10 patients were enrolled in the pilot study. The patients were generally satisfied with the diary, found that it involved them more in their treatment and made it easier to set personal goals, and found it worth the time spent using it. However, no clear advantage in relation to their quality of life (WHO-QoL BREF and WHO-5 well-being score) was reported. International Journal of Rehabilitation Research 40:175–184 Copyright © 2017 The Author(s). Published by Wolters Kluwer Health, Inc.

Keywords: botulinum toxins, delivery of health care, goals, muscle spasticity, rehabilitation, treatment diary

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Introduction

Botulinum toxin skeletal muscle injection treatment is long-lasting and monitored dependent on individual effects (Mancini et al., 2005; Bakheit et al., 2010). Problems such as pain, co-contraction, spastic dystonia, flexor spasms, etc. triggered by muscle overactivity/spasticity often have a huge impact on the individual's quality of life (QoL) (Hefter et al., 2012; Milinis et al., 2016). Accurate and detailed reporting of these effects is therefore crucial (Bakheit et al., 2010). Often, several health care professionals are involved in the patient's treatment and important information is easily lost (Demetriou et al., 2013). A patient diary may increase the patient's awareness of problems triggered by muscle overactivity and may help the patient to evaluate the treatment better. This should result in more appropriate treatment goals for the individual patient and ultimately lead to higher QoL. 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 final optimization of the treatment.

Patient diaries have been used in various neurological fields, including headache (Russell et al., 1992, 1994; Allena et al., 2012; Seidel et al., 2012; Stinson et al., 2013; Larsson and Fichtel, 2014; Barmettler et al., 2015; Heyer and Rose, 2015; Pasek et al., 2015), epilepsy (Le et al., 2011; Haut et al., 2013; Cobabe et al., 2015; Fisher et al., 2015), sleep, other pain, etc. (Le et al., 2011; Jacob et al., 2012). Several of these have been in the form of electronic diaries (Haut et al., 2013; Stinson et al., 2013; Barmettler et al., 2015; Pasek et al., 2015), including online (Fisher et al., 2015), web-based (Le et al., 2011) through the internet (Heyer and Rose, 2015), on-palm device (Allena et al., 2012), and smartphone (Jacob et al., 2012).

The prospective paper diary has been compared with a retrospective questionnaire for headache, and the results suggested that more valid and reliable results would be obtained using the prospective diary (Larsson and Fichtel, 2014).

The aim of this pilot study was primarily to develop a diary that constantly follows the patient in treatment with botulinum toxin skeletal muscle injections for spasticity.

Methods and results

Content of the treatment diary (Appendix)

1. Problems triggered by skeletal muscle overactivity.
Two of the patients admitted not having used the diary or completed the diary, and have answered "no" to nearly all questions; these are given in brackets.

| Question                                                                 | 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 (2) |
| Is it easier to set personal goals for treatment when you use the diary? | 5 (2) | 2 (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 (2) |
| Are all parties involved in your treatment better informed about you and your treatment when you use the diary? | 6 (1) | 2 (2) |
| Is the diary worth applying in relation to the time that you had to spend on it? | 7 (1) | 0 (2) |
| Allows use of the diary you a higher quality of life?                    | 4 (2) | 3 (2) |

Table 1 Answers (yes/no) in numbers from the nine patients who filled in the satisfaction questionnaire related to the spasticity diary

In Table 1 the patients’ responses to the Satisfaction questionnaire are shown. Among those who used the diary, 86% (6/7) found that they were more involved in their treatment and it was easier to set personal goals for treatment with this tool. In addition, all participants who used the diary found it worth the time spent using it.

Table 2 lists the scores to the answers to the WHO-QoL BREF and WHO-5 well-being.

Some patients and therapists reported that they had misunderstood how to complete the diary and needed more clear instructions.

Further developments of the treatment diary

(1) Feedback from the patients and therapists showed that the diary should be simplified and more clear instructions should be provided.
(2) The new diary was then presented during three workshops with around 70 physicians, physiotherapists, occupational therapists, and nurses.
(3) Translation of the diary from Danish into English included adjustments, making the diary more easily comprehensible and useable.

Translation

The translation process included both language translation and cultural adaptation (Price et al., 2009). Therefore, the translation of the Treatment Diary from the original Danish version into English was not purely made word for word, but we aimed to include conceptual equivalence. It is the meaning of the content in the original Danish version of the diary that should be translated. The translation had to similarly be concise, clear, and simple, whereas terms, jargon, and abbreviations that are not easily understood were avoided.

The initial translation was made by F.B.S., and afterwards, the translation was checked by B.B.S. and H.K.I. The ‘checkers’ did not provide another translation, but had to report whether the translation of the diary was sufficient to convey the original concepts (Biering-Sørensen et al., 2011). Where there were disagreements, the three translators came to a consensus on which translations would be the most appropriate. Finally, the translation was scrutinized by a bilingual person (English/Danish) with knowledge of the field and minor adjustments were made.

Two of the patients admitted not having used the diary or completed the diary, and have answered "no" to nearly all questions; these are given in brackets.

Development of the treatment diary

(1) A focus group with physicians, a physiotherapist, a nurse, and a representative from Allergan Pharmaceuticals discussed the primary elements to be included.
(2) Inspiration was gained from meetings with therapists from rehabilitation centers.
(3) The first version was developed.
(4) This edition was presented to a focus group. Because of the feedback, some of the formulations were changed to make them more easily understandable.

Pilot testing

A protocol for a Pilot study was submitted to the National Committee on Health Research Ethics and it was approved by the Danish Data Protection Agency (GLO-2014-30, I-suite 02998).

The pilot study enrolled ten patients after their oral and written informed consent was obtained. The evaluation also included the use of the Danish translations of the WHO-QoL BREF (http://www.cure4you.dk/960/WHOQoL-Bref%20-%20dansk.pdf; http://depts.washington.edu/seaqol/docs/WHOQOL-BREF%20with%20scoring%20instructions_Updated%202011–10–14.pdf) and the WHO-5 well-being score (https://wwwpsykiatri-regionh.dk/who-5/Documents/WHO5_Danish.pdf; Topp et al., 2015). These were to be completed before and after the use of the diary over an ~3-month period between two botulinum toxin injection cycles. The patient and the therapist were asked to fill in a questionnaire on the usefulness of the treatment diary and suggestions on how to make the diary better.

Results of pilot testing

Ten patients completed the study, but one lost the spasticity diary.

(2) Agreed goals for treatment and the patient’s continuous self-evaluation of achievement of objectives on the Goal Attainment Scale (Turner-Stokes, 2009).
(3) Which skeletal muscles were injected and the botulinum toxin dose administered.
(4) Physiotherapists’ and occupational therapists’ evaluation of the patients’ achievement of objectives on the Goal Attainment Scale as well as proposals for optimization of treatment and changing goals.
WHO-5 well-being score (all questions rated 5 to 0)

The patient and the therapist to write their evaluations of the treatment and suggestions for optimization of the treatment. An electronic version might lead to obstacles when the patient and different health care professionals require access to the same e-diary. In the future, we hope that it will be possible to develop an e-version where data security challenges can be solved.

Conclusion

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.

A study evaluating the revised treatment diary is ongoing. The publication of this English version is because of requests from physicians, caregivers, patients, and therapists in Nordic Countries to enable quick use of the diary.

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Conflicts of interest

Bo Biering-Sørensen has received honoraria for lectures from IPSEN, Allergan, Abbvie, UCB Pharma, and Berlin-Chemie AG, received honoraria for participating in Advisory Boards for IPSEN, Allergan, Merz, and Abbvie, and received an unconditional grant for this study from Allergan. Helle Klingenberg Iversen, Inge Mona Schack Frederiksen, and Jeanet Roger Vilhelmsen have received honoraria for lectures from IPSEN. For the remaining author there are no conflicts of interest.

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Appendix

Treatment Diary

Start date:
Year:

Participant ID:

First name:

Surname:

Patient ID number:

Contact, physician:

Contact, nursing staff:

Department /Clinic

Address

Telephone – and days/hour for contact
Dear Patient,

As part of your rehabilitation you receive treatment with botulinum toxin. Please read the patient information provided by your physician regarding botulinum toxin.

This treatment diary is a tool to help you, your care providers and rehabilitation network (doctors, physiotherapists, occupational therapists, etc.) to improve the management of your rehabilitation.

The purpose of the treatment diary is also to assess the effect of your treatment and improve outcomes.

Important

The treatment is given as injections in selected muscles. For maximum rehabilitation you should regularly, once a week on the same weekday, evaluate the treatment compared to specific goals that you, together with your care provider, agree are important to focus on.

For this purpose, please fill in the tables on pages 4-7.

The answers, notes and comments in the treatment diary can help you and your care provider assess whether the treatment is living up to expectations and if you are reaching the goals that you, together with your care provider, jointly set before starting treatment.

Sincerely

Clinic / Department

Your personal goals

1. Set yourself 1-2 personal goals. For example brushing teeth without assistance, wash under arms, walk 100 meters with a cane or equivalent. NB: The goals must be different!

Goal 1

| Describe goal 1: | Starting point: |
|-----------------|----------------|
|                 |                |

2. Every week (on the same weekday and at weekly intervals) you must evaluate how you develop compared to the goal. Always compare with the starting point that corresponds to the “Slightly worse than goal” in the table below. Indicated with a cross at “Week 0”.

| Week 0 | Week 1 | Week 2 | Week 3 |
|--------|--------|--------|--------|
| Date   |        |        |        |
| Much better than goal |        |        |        |
| A little better than goal |        |        |        |
| Goal achieved |        |        |        |
| Slightly worse than goal | x       |        |        |
| Much worse than goal |        |        |        |

3. Mark with a cross how you are compared to Week 0 (starting point), and note the date.

NOTE: Write also the goals on pages 12-13, for your therapist to know them.
Your personal goals

Goal 2

Describe goal 2:
Starting point:

|       | Week 0 | Week 1 | Week 2 | Week 3 |
|-------|--------|--------|--------|--------|
| Date  | 4      |        |        |        |
| Much better than goal |        |        |        |        |
| A little better than goal |        |        |        |        |
| Goal achieved |        |        |        |        |
| Slightly worse than goal | X    |        |        |        |
| Much worse than goal |        |        |        |        |

|       | Week 4 | Week 5 | Week 6 | Week 7 |
|-------|--------|--------|--------|--------|
| Date  | 8      |        |        |        |
| Much better than goal |        |        |        |        |
| A little better than goal |        |        |        |        |
| Goal achieved |        |        |        |        |
| Slightly worse than goal |        |        |        |        |
| Much worse than goal |        |        |        |        |

|       | Week 8 | Week 9 | Week 10 | Week 11 |
|-------|--------|--------|---------|---------|
| Date  | 12     |        |         |         |
| Much better than goal |        |        |         |         |
| A little better than goal |        |        |         |         |
| Goal achieved |        |        |         |         |
| Slightly worse than goal |        |        |         |         |
| Much worse than goal |        |        |         |         |

Have you had any side effects?

Have you had any side effects associated with your treatment?

No □ Yes □

If yes, please describe what kind of side effects you have had:

If you experience any side effects associated with your treatment with botulinum toxin, you should contact your doctor.

Other notes concerning the treatment

Comments:

__________________________________________________________________________________________

__________________________________________________________________________________________

__________________________________________________________________________________________

__________________________________________________________________________________________
## Treatment synopsis

(to be filled in by the physician)

**Date/year of examination:**

**Injection guidance technique:**

- Ultrasound
- EMG
- Stimulation

**Diagnosis:**

**Possible comments to the diagnosis:**

**Botulinum toxin (BTX) injected by (physician name):**

**Botulinum toxin trade name:**

| Injection sites | Sde | Muscle | No. BTX units |
|-----------------|-----|--------|---------------|
| R | L | | |
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| R | L | | |

Glossary of abbreviations in muscle overview on the back cover.

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## Rehabilitation

(to be filled in by the therapist)

The patient has set 1-2 personal goals for his/her treatment. Between the two botulinum toxin treatments (approximately 3 months) you are asked to evaluate how the patient progresses compared (or relatively) to the starting point (indicated with a cross at “Week 0” for “Slightly worse than goal” in the tables below). You are asked to evaluate and mark with a cross for the start phase, mid-phase, and final phase respectively.

**Goal 1**

**Description goal 1:**

**Starting point:**

| Week 0 | Start phase Date | Mid phase Date | Final phase Date |
|--------|------------------|----------------|------------------|
| Much better than goal | | | |
| A little better than goal | | | |
| Goal achieved | | | |
| Slightly worse than goal | x | | |
| Much worse than goal | | | |

**Goal 2**

**Description goal 2:**

**Starting point:**

| Week 0 | Start phase Date | Mid phase Date | Final phase Date |
|--------|------------------|----------------|------------------|
| Much better than goal | | | |
| A little better than goal | | | |
| Goal achieved | | | |
| Slightly worse than goal | | | |
| Much worse than goal | | | |

Comments:
Rehabilitation

| How often does the patient receive therapist administered exercise? |
|---------------------------------------------------------------|
| Daily                                                        |
| 3-4 times per week                                            |
| 1-2 times per week                                            |

| How often does the patient exercise him-/herself?            |
|-------------------------------------------------------------|
| Daily                                                       |
| 3-4 times per week                                          |
| 1-2 times per week                                          |
| Use guided self-rehabilitation (GSR)                        |
| Does not exercise him-/herself                              |

How/where is the rehabilitation performed?

| At hospital                                              |
| At municipal institution                                |
| Outpatient, individual rehabilitation, through their general practitioner |
| Outpatient, team training, through their general practitioner |

Evaluation of the treatment

| Physiotherapist name: |
|-----------------------|
| Physiotherapists telephone no.: |

Are there other treatment goals that you and the patient finds relevant?

| Yes ☐ No ☐ If yes, which? |

Are there other muscles or muscle groups that might benefit from being treated with botulinum toxin when trying to reach the goal:

| Yes ☐ No ☐ If yes, which? |

Other remarks

| Comments: |
|-----------|
|-----------|
|-----------|
|-----------|
|-----------|

| Occupational therapist name: |
|-----------------------------|
| Occupational therapists telephone no.: |

Are there other treatment goals that you and the patient finds relevant?

| Yes ☐ No ☐ If yes, which? |

Are there other muscles or muscle groups that might benefit from being treated with botulinum toxin when trying to reach the goal:

| Yes ☐ No ☐ If yes, which? |

Other remarks
Next appointment

Your next appointment in the clinic:

Date: ______________________  Time: ______________________

| Upper extremity | Lower extremity |
|-----------------|-----------------|
| ADP             | AB              |
| APL             | AL              |
| BA              | AM              |
| BI              | BF              |
| BR              | ECR             |
| ECU             | ECT             |
| ED              | EDL             |
| EPB             | EHL             |
| EPL             | FDL             |
| FCR             | FHL             |
| FCU             | GA-L            |
| FDP             | GA-M            |
| FDS             | Gmax            |
| FPB             | GR              |
| FPL             | IP              |
| INT             | RF              |
| LUM             | SM              |
| Pec             | SO              |
| PT              | ST              |
|                 | TA              |
|                 | TP              |
|                 | VI              |
|                 | VL              |
|                 | VM              |

Muscle overview

Notes

________________________
________________________
________________________

Thanks for your participation

Department /Clinic:
Address:
Telephone – and days/hour for contact: