

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* 00:000–000 Copyright © 2017 The Author(s). Published by Wolters Kluwer Health, Inc.

International Journal of Rehabilitation Research 2017, 00:000–000

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

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Received 18 November 2016 Accepted 24 January 2017

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) (Heftner *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 (Demetrios *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 on-line (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.

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

	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)

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.

- (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.

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%2001-10-14.pdf) and the WHO-5 well-being score (https://www.psykiatri-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.

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, physiotherapist, occupational therapist, 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.

Table 2 Average and range of answers to WHO-QoL-bref and WHO-5 well-being score questions from 10 patients before and after being treated with botulinum toxin. For one patient, no answers are available after the treatment

	Before average (range) (N = 10)	After average (range) (N = 9)	P-value ^a
WHO-QoL-bref (all questions rated 1 to 5)			
How would you rate your quality of life?	3.7	3.6	0.77
How satisfied are you with your health?	3.1	3.2	0.77
To what extent do you feel that physical pain prevents you from doing what you need to do?	2.6	2.5	0.97
How much do you need medical treatment to function in your daily life?	1.7	2.0	0.46
How much do you enjoy life?	3.2	3.6	0.97
To what extent do you feel life to be meaningful?	3.5	3.4	0.90
How well are you able to concentrate?	3.9	4.1	0.62
How safe do you feel in your daily life?	3.8	3.7	0.74
How healthy is your physical environment?	2.3	2.7	0.44
Do you have enough energy for everyday life?	3.7	3.3	0.40
Are you able to accept your bodily appearance?	3.4	3.3	0.81
To what extent do you have enough money to meet your needs?	4.0	4.1	0.94
How available to you is the information that you need in your day-to-day life?	4.5	3.9	0.33
To what extent do you have the opportunity for leisure activities?	2.0	2.1	0.97
How well are you able to get around?	3.4	3.3	0.94
How satisfied are you with your sleep?	3.4	3.1	0.60
How satisfied are you with your ability to perform daily living activities?	3.5	3.2	0.60
How satisfied are you with your capacity for work?	3.6	3.6	0.97
How satisfied are you with yourself?	3.1	3.6	0.94
How satisfied are you with your personal relationships?	4.1	4.1	0.94
How satisfied are you with your sex life?	2.9	2.8	0.87
How satisfied are you with the support you get from your friends?	3.6	3.9	0.71
How satisfied are you with the conditions of your living place?	4.4	4.3	0.90
How satisfied are you with your access to health services?	4.0	3.8	0.71
How satisfied are you with your transport?	4.3	3.9	0.29
How often do you have negative feelings, such as blue mood, despair, anxiety, depression?	2.2	2.1	0.84
Overall Quality of Life and General Health – Questions 1,2 ^b	6.8	6.8	1.0
Domain I (physical) Questions 3,4,10,15,16,17,18 ^b	25.0	24.3	0.78
Domain II (Psychological) Questions 5,6,7,11,19,26 ^b	22.0	23.0	0.68
Domain III (social relationships) Questions 20,21,22 ^b	10.5	10.6	0.97
Domain IV (environment) Questions 8,9,12,13,14,23,24,25 ^b	29.7	28.0	0.31
WHO-5 well-being score (all questions rated 5 to 0)			
Over the past 2 weeks			
I have felt cheerful and in good spirits	3.3	3.3	0.87
I have felt calm and relaxed	3.3	3.4	1.0
I have felt active and vigorous	2.4	2.2	0.87
I woke up feeling fresh and rested	2.8	2.3	0.57
My daily life has been filled with things that interest me	3.0	3.1	0.93
Final score ^c	58.0	57.3	0.87

^aThe tests are performed with the Mann–Whitney test using <http://vassarstats.net/> for direct import/entry of data for analyses. Two sided P-values are given.

^bhttp://depts.washington.edu/seaqol/docs/WHOQOL-BREF%20with%20scoring%20instructions_Updated%2001-10-14.pdf.

^cScoring principle: The sum of the 5 raw scores ranging from 0 to 25 is multiplied by 4 to yield the final score, with 0 representing the worst imaginable well-being to 100 representing the best imaginable well-being (Topp *et al.*, 2015).

Discussion

Feedback from colleagues shows that physicians and therapists find inputs from patients and all health care professionals involved helpful and important for the treatment success. The fact that the therapist and the patient/caregiver together have the opportunity to choose other relevant treatment goals and communicate these to the physician using the treatment diary was highlighted as the botulinum toxin injections or other spasticity treatment can be adjusted according to these new goals.

If the patient cannot cooperate with goal setting or evaluation of the treatment, a caregiver or a relative taking care of the patient can help to set relevant goals and evaluate whether the goals are reached.

The reason having the treatment diary in paper was to make it easier for the patient to carry around and allowed 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.

Acknowledgements

The authors like to thank senior consultants Stephen W. Pedersen and Jesper Bøje Clausen for initial inspiration for this work. The patients and the therapists are thanked for their participation in the pilot project and their useful comments to improve the treatment diary.

Allergan A/S has provided unconditional grant supporting the production of the treatment diary.

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

INTRODUCTION	3
PATIENT	
Your personal goals	4
PHYSICIAN	
Notes regarding treatment	10
PHYSIO- AND OCCUPATIONAL THERAPIST	
Rehabilitation	12
NEXT APPOINTMENT	16

Introduction

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!*
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".

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.

Goal 1

Describe goal 1:
Starting point:

	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				

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

	Week 12	Week 13	Week 14	Week 15
Date				
Much better than goal				
A little better than goal				
Goal achieved				
Slightly worse than goal				
Much worse than goal				

	Week 16	Week 17	Week 18	Week 19
Date				
Much better than goal				
A little better than goal				
Goal achieved				
Slightly worse than goal				
Much worse than goal				

Comments:

Your personal goals

Goal 2

Describe goal 2:

Starting point:

	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				

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

6

	Week 12	Week 13	Week 14	Week 15
Date				
Much better than goal				
A little better than goal				
Goal achieved				
Slightly worse than goal				
Much worse than goal				

	Week 16	Week 17	Week 18	Week 19
Date				
Much better than goal				
A little better than goal				
Goal achieved				
Slightly worse than goal				
Much worse than goal				

Comments:

7

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.

8

Other notes concerning the treatment

9

Treatment synopsis

(to be filled in by the physician)

Date/year of examination:	Injection guidance technic: Ultrasound <input type="checkbox"/> EMG <input type="checkbox"/> Stimulation <input type="checkbox"/>
Diagnosis:	
Possible comments to the diagnosis:	
Botulinum toxin (BTX) injected by (physician name):	
Botulinum toxin trade name:	

10

Spasticity treatment with botulinum toxin

in the following muscles:

Injection sites		
Side	Muscle	No. BTX units:
R <input type="checkbox"/> L <input type="checkbox"/>		
R <input type="checkbox"/> L <input type="checkbox"/>		
R <input type="checkbox"/> L <input type="checkbox"/>		
R <input type="checkbox"/> L <input type="checkbox"/>		
R <input type="checkbox"/> L <input type="checkbox"/>		
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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 relative) 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.

Evaluation of the patient's goal

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				

Comments:

12

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	x			
Much worse than goal				

Comments:

13

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

Comments:

14

Evaluation of the treatment

Physiotherapist

Physiotherapists 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

Occupational therapist

Occupational therapists 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

15

Next appointment

Your next appointment in the clinic:

Date: _____

Time: _____

Muscle overview

Upper extremity

ADP	Adductor pollicis
APL	Abductor pollicis longus
BA	Brachialis
BI	Biceps Brachii
BR	Brachioradialis
ECR	Extensor carpi radialis
ECU	Extensor carpi ulnaris
ED	Extensor digitorum
EPB	Extensor pollicis brevis
EPL	Extensor pollicis longus
FCR	Flexor carpi radialis
FCU	Flexor carpi ulnaris
FDP	Flexor digitorum profundus
FDS	Flexor digitorum superficialis
FPB	Flexor pollicis brevis
FPL	Flexor pollicis longus
INT	Interosus
LUM	Lumbricalis
Pec	Pectoralis major
PT	Pronator teres

Lower extremity

AB	Adductor brevis
AL	Adductor Longus
AM	Adductor magnus
BF	Biceps femoris
EDL	Extensor digitorum longus
EHL	Extensor hallucis longus
FDL	Flexor digitorum longus
FHL	Flexor hallucis longus
GA-L	Gastrocnemius lateral
GA-M	Gastrocnemius medial
Gmax	Gluteus maximus
GR	Gracilis
IP	Iliopsoas
RF	Rectus femoris
SM	Semimembranosus
SO	Soleus
ST	Semitendinosus
TA	Tibialis anterior
TP	Tibialis posterior
VI	Vastus intermedius
VL	Vastus lateralis
VM	Vastus medialis

Notes

Thanks for your participation

Department /Clinic:

Address:

Telephone – and days/hour for contact: