

University of Groningen

Assessment of change in clinical evaluation

Middel, Lambertus Johannes

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version

Publisher's PDF, also known as Version of record

Publication date:

2001

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

Middel, L. J. (2001). *Assessment of change in clinical evaluation*. s.n.

Copyright

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: <https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment>.

Take-down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

Assessment of change in clinical evaluation

Middel, L.J.

Assessment of change in clinical evaluation

Thesis University Groningen with summary in Dutch

ISBN 90 72156 94 3

© 2001 L.J. Middel. All rights reserved. No part of this book may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, without written permission from the author.

Cover design: Mickey ©

Printed by Stichting Drukkerij C. Regenboog, Groningen

RIJKSUNIVERSITEIT GRONINGEN

ASSESSMENT OF CHANGE IN CLINICAL EVALUATION

Proefschrift

Ter verkrijging van het doctoraat in de Medische Wetenschappen
aan de Rijksuniversiteit Groningen op gezag van de
Rector Magnificus, dr. D.F.J. Bosscher,
in het openbaar te verdedigen op
woensdag 10 oktober 2001 om 16.00 uur

Door

Lambertus Johannes Middel
Geboren op 12 augustus 1946
te Groningen

Promotor: Prof. Dr. W.J.A. van den Heuvel

Referent: Dr. M.J.L. de Jongste

Promotiecommissie: Prof. Dr. D. Post
Prof. Dr. J.L. Peschar
Prof. Dr. H.J.G.M. Crijns

Paranimfen: Bert Hamersma
Jan Just Middel

Damit das Mögliche entsteht,

Muss immer wieder das Unmögliche versucht werden

Hermann Hesse

Voor Aukje en Elke

Contents

1. Introduction	
1.1 General introduction	10
1.2 Objectives and main research questions of this thesis	11
1.3 Terms and definitions	15
1.4 Estimates of clinically relevant change	21
2. Effect of intrathecal baclofen delivered by an implanted programmable pump on health related quality of life in patients with severe spasticity	
2.1 Introduction	36
2.2 Methods	36
2.3 Results	40
2.4 Discussion	46
2.5 Conclusion	47
3. Psychometric properties of the Minnesota Living with Heart Failure - Questionnaire (MLHF-Q).	
3.1 Introduction	53
3.2 Methods	54
3.3 Results	57
3.4 Discussion	66
4. How to interpret the magnitude of change in health-related quality of life? A study on the use of Cohen's thresholds for effect size estimates.	
4.1 Introduction	73
4.2 Materials and methods	76
4.3 Results	89
4.4 Discussion	84
5. How to validate clinically important change in health-related functional status. Is the magnitude of the effect size consistently related to magnitude of change as indicated by a global question rating?	
5.1 Introduction	95
5.2 Patients and methods	98
5.3 Determination of concordance between two intervals of magnitude of change	100
5.4 Results	103
5.5 Analysis	106
5.6 Discussion	113

6. Why don't we ask patients with coronary artery disease directly how much they have changed after treatment?

Comparison of retrospective multi-item change scales with serial change in domains A of health related functional status.

6.1	Introduction	121
6.2	Methods	123
6.3	Results	127
6.4	Discussion	138

7. Conclusions and discussion

7.1	Introduction	144
7.2	Main results and consequences for methodology of assessing change in HRFS	144
7.3	Recommendations for practice and research	152

8. Summary 157

9. Samenvatting 164