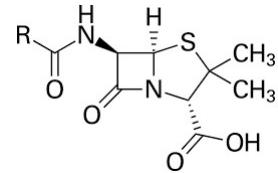




It's about 100 years ago



But what if he lived in 2021?

Webinar MDR - VR4REHAB - ©RLuigies



1



What if this was designed in 2021?



Webinar MDR - VR4REHAB - ©RLuigies



2



PEDIATRICS®

Articles ▾ Authors/Reviewers ▾ Policy ▾

Volume 122, Issue 2

August 2008



ARTICLES | AUGUST 01 2008

A Video Game Improves Behavioral Outcomes in Adolescents and Young Adults With Cancer: A Randomized Trial

Pamela M. Kato, PhD, EdM; Steve W. Cole, PhD; Andrew S. Bradlyn, PhD; Brad H. Pollock, PhD, MPH

Address correspondence to Pamela M. Kato, PhD, EdM, University Medical Center Utrecht, Center for Patient Safety, Housepost number Q 05.4.300, PO Box 85500, 3508 GA Utrecht, Netherlands. E-mail: pkato@umcutrecht.nl
Pediatrics (2008) 122 (2): e305–e317.

<https://doi.org/10.1542/peds.2007-3134> Article history

Share ▾

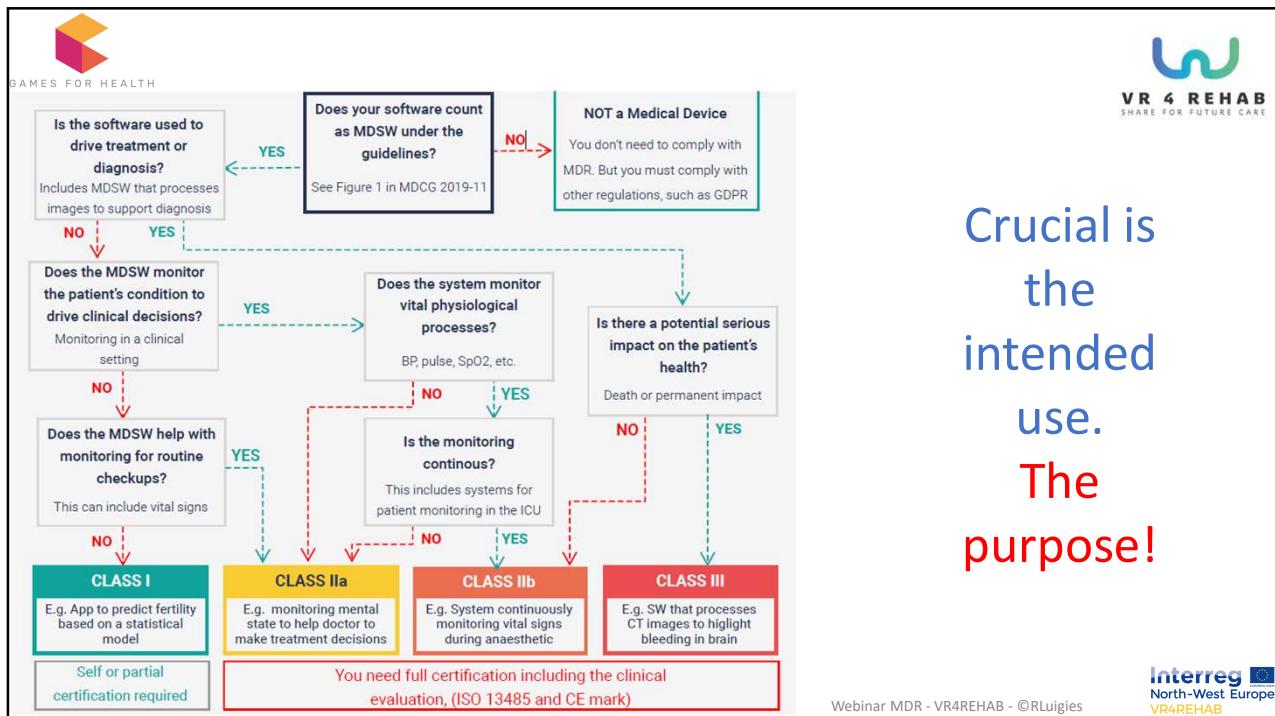
Tools ▾

OBJECTIVE. Suboptimal adherence to self-administered medications is a common problem. The purpose of this study was to determine the effectiveness of a video-game intervention for improving adherence and other behavioral outcomes for adolescents and young adults with malignancies including acute leukemia, lymphoma, and soft-tissue sarcoma.

Webinar MDR - VR4REHAB - ©RLuigies



3



4

What if not Class I ?

What is the risk of harm?	Significance of the information		
	Treat or diagnose	Drive clinical management	Inform treatment
	Critical	Class III	Class IIb
	Serious	Class IIb	Class IIa
Other	Class IIa	Class IIa	Class IIa



Webinar MDR - VR4REHAB - ©RLuigies

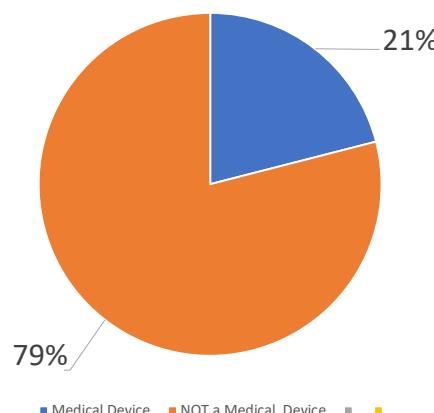
Interreg  North-West Europe
VR4REHAB

5

Existing Apps n = 271



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport



Webinar MDR - VR4REHAB - ©RLuigies

Interreg  North-West Europe
VR4REHAB

6



What about new games, to be designed?



What do I want as purpose?
 Can I avoid the MDR?
 Can I afford the MDR?
 What options are there?

Webinar MDR - VR4REHAB - ©RLuigies



7



Purpose: Catching monsters

Effect: More fysical activity

Fysical activity contributes to prevention of CVD, Diabetes, etc.

➤ Which is a derivative of fysical activities

What if PG's intended purpose was defined as prevention?

Webinar MDR - VR4REHAB - ©RLuigies



8



First Dutch Nintendo Switch game

Purpose: Team Building / Socializing of youngsters

Effect: More and improved communications

Side effect: Improved communication skills for autism!

What if TT's intended purpose was treatment of autism?

Webinar MDR - VR4REHAB - ©RLuigies



9



Some tips



Sponsor



Healthy Bones App



Embedded in Portal



Other party's money



Webinar MDR - VR4REHAB - ©RLuigies

10



GAMES FOR HEALTH

Clear intended purpose



VR 4 REHAB
SHARE FOR FUTURE CARE



INSIGHTTM ADHD
our behavior tracking app

AKIKI ASSIST
our online support service and call center

EndeavorTM

Webinar MDR - VR4REHAB - ©RLuigies



Interreg
North-West Europe
VR4REHAB

11



GAMES FOR HEALTH

FDA Permits Marketing of First Game-Based Digital Therapeutic to Improve Attention Function in Children with ADHD



VR 4 REHAB
SHARE FOR FUTURE CARE

[f Share](#) [t Tweet](#) [in LinkedIn](#) [Email](#) [Print](#)

For Immediate Release: June 15, 2020

[Español](#)

Today, the U.S. Food and Drug Administration (FDA) permitted marketing of the first game-based digital therapeutic device to improve attention function in children with attention deficit hyperactivity disorder (ADHD). The prescription-only game-based device, called EndeavorRx, is indicated for pediatric patients ages 8 to 12 years old with primarily inattentive or combined-type ADHD who have demonstrated an attention issue. EndeavorRx is indicated to improve attention function as measured by computer-based testing and is the first digital therapeutic intended to improve symptoms associated with ADHD, as well as the first game-based therapeutic granted marketing authorization by the FDA for any type of condition. **The device is intended for use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs, which further address symptoms of the disorder.**

"The EndeavorRx device offers a non-drug option for improving symptoms associated with ADHD in children and is an important example of the growing field of digital therapy and digital therapeutics," said Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "The FDA is committed to providing regulatory pathways that enable patients timely access to safe and effective innovative digital therapeutics."



Interreg
North-West Europe
VR4REHAB

12



The dream of all

Maker Of \$295 Prescription Video Game For Kids With ADHD To Go Public In Palihapitiya-Led SPAC Deal

Webinar MDR - VR4REHAB - ©RLuigies



13



It all seems a labyrinth



Above all



Webinar MDR - VR4REHAB - ©RLuigies



14



GAMES FOR HEALTH



VR 4 REHAB
SHARE FOR FUTURE CARE

Some literature



MDR and digital health
How to build MDR compliant applications

<https://www.chino.io/a/chino-io-ebook-medical-device-regulation-ehealth-applications>



Medical Device Software under the MDR
Qualification and Classification of Software as a medical device

Annette I. van Raamdonk, LL.M.
Senior Regulatory Affairs Consultant, Emergo
TFHC, May 19th 2021

 EMERGO

Webinar MDR - VR4REHAB - ©RLuigies

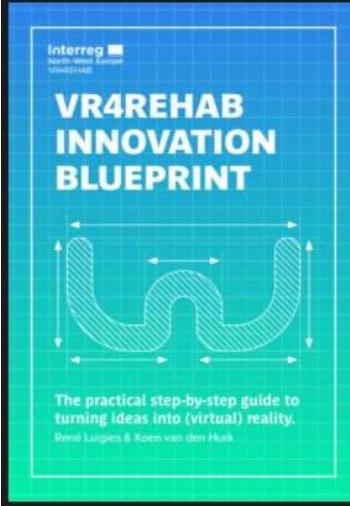
15



GAMES FOR HEALTH



VR 4 REHAB
SHARE FOR FUTURE CARE



VR4REHAB INNOVATION BLUEPRINT
The practical step-by-step guide to turning ideas into (virtual) reality.
René Luigies & Koen van den Huk

Get access!

Would you like to download our blueprint? Please leave your email address and get access to the download.

Get access

<https://vr4rehab.org/blueprint/>

Webinar MDR - VR4REHAB - ©RLuigies

16



GAMES FOR HEALTH



Thank you for your attention!
and
Good luck!

rene@gamesforhealth.net

<https://www.linkedin.com/in/reneluigies/>

Webinar MDR - VR4REHAB - ©RLuigies

