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PCMG
Pharmaceutical Contract Management Group

Serious games and gamification in clinical trials

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What are serious games and gamification?

Serious games

A game designed for a primary purpose other than entertainment

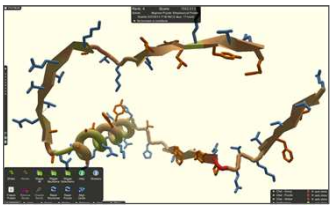
Gamification

The use of video game elements to improve user experience and user engagement in non-games services and applications

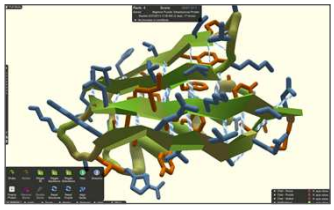
Example

Foldit (https://fold.it/portal/)

- Foldit attempts to predict the structure of a protein by taking advantage of humans' puzzle-solving intuitions and having people play competitively to fold the best proteins
- Since proteins are part of so many diseases, they can also be part of the cure. Players can design brand new proteins that could help prevent or treat important diseases



Unfolded Streptococcal protein puzzle



Folded up Streptococcal protein puzzle

Serious games and gamification in clinical trials

- Games for subject education and recruitment
- Gamification for patient engagement / retention and motivating other trial participants
- Games to measure objective health outcomes
- Future direction

Current use of games and gamification in trials

1. Learning about clinical research

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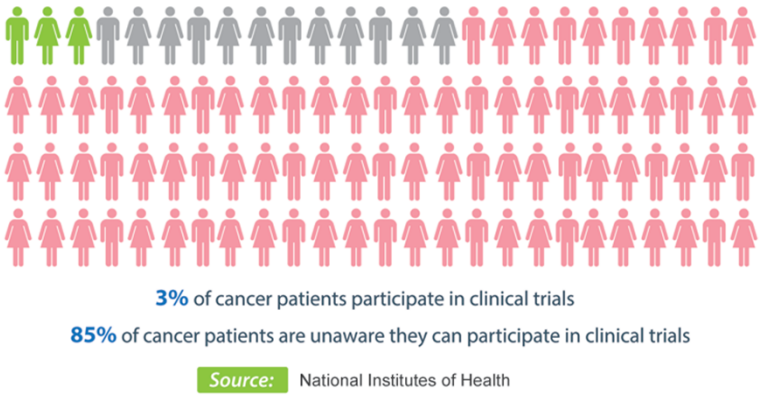
Challenges: patient recruitment



80% of studies fail to meet recruitment timelines

30% of sites fail to recruit a single patient

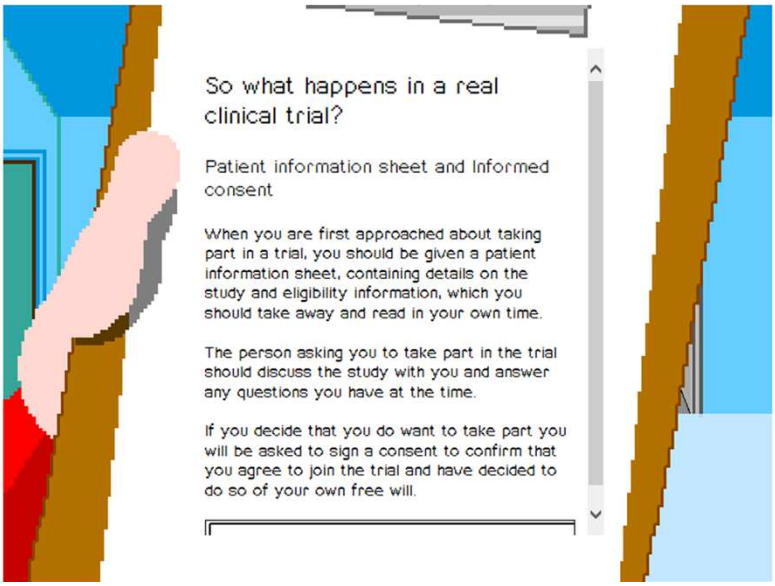
Study delays cost $37,000 per day in direct costs.

Learning about clinical research

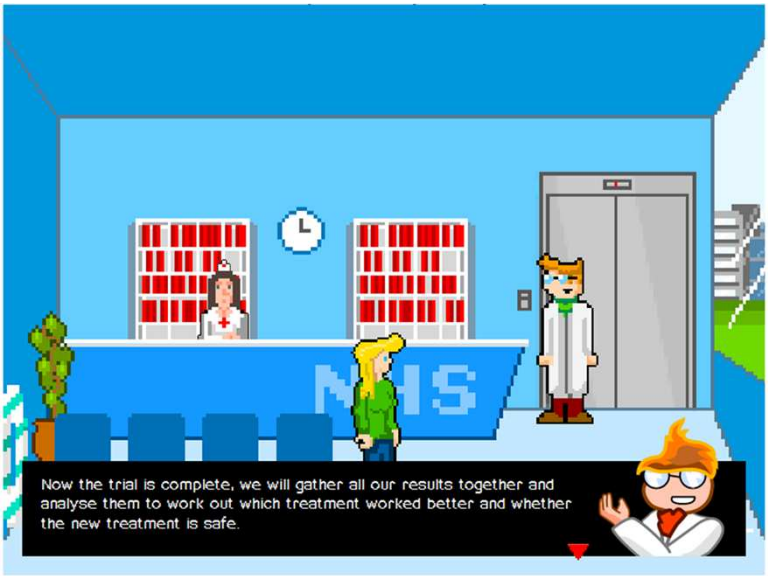
- Testing a medicine that can make you fly
- Go through the stages in a clinical trial
- Understand what's typically involved
- Understand trial terms, e.g. "blinded trial"
- After playing the game, 90% indicated they would be interested in participating in a real study.

NHS
National Institute for Health Research
Clinical Research Network

Learning about clinical research



Learning about clinical research



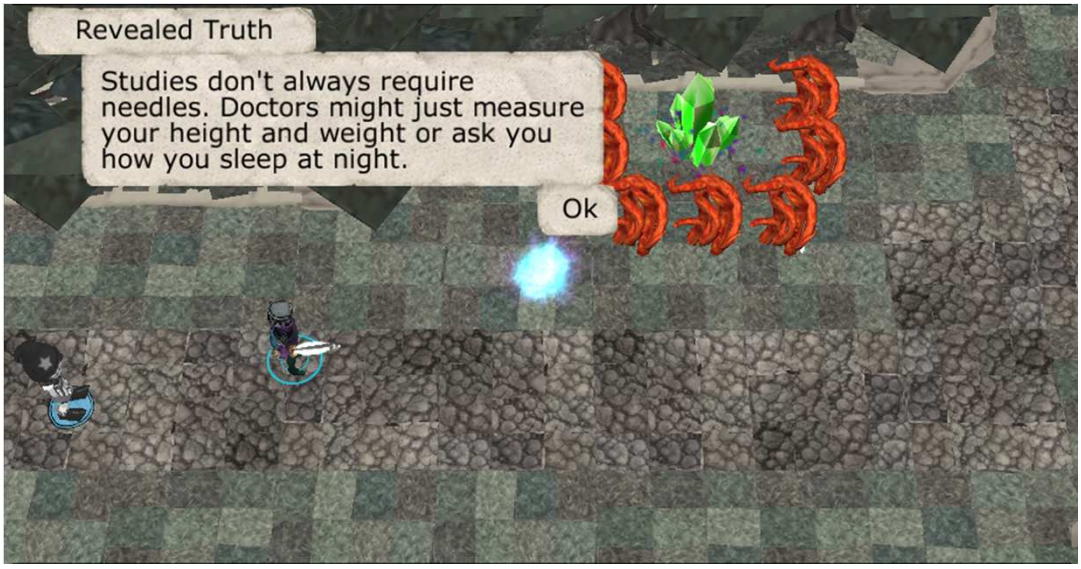
Learning about clinical research

neri
New England Research Institutes

- Aimed at alleviating fears of children (8 – 14y) and their parents about clinical trials
- Fantasy game –rescue brother from fantasy world
- Defeat dragons to dispel fears and myths about trials
- A study in 250 children:
  - Users of the video game increased their knowledge
  - Control group (paper information sheet) was superior.

Learning about clinical research

Learning about clinical research



Learning about clinical research

Considerations

- Interactive game-based learning may be a particularly effective approach for the millennials and generation Z
  - Multiple streams of information, prefer inductive reasoning, want frequent and quick interactions with content, and have exceptional visual literacy skills [1]
- Learning that occurs in meaningful and relevant contexts is more effective than learning that occurs outside these contexts. [1]

[1] R. Van Eck, "Digital game-based learning: it's not just the digital natives who are restless," EDUCAUSE Review, 41: 16-30, March/April 2006.

Current use of games and gamification in trials

2. Gamification

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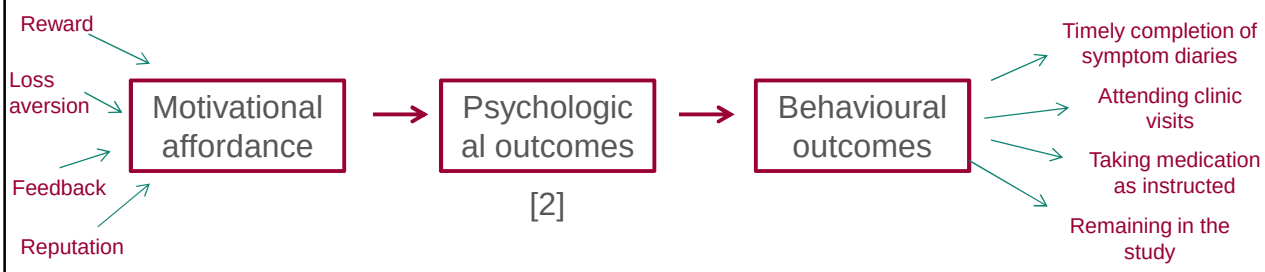
Challenges: patient retention

- Average drop out rates: 15-40%
- Patients can withdraw consent at any time
- Some patients are lost to follow up.

> "In 2014, the US FDA declined to approve an application for the wider use of Xarelto, a blood clot preventing medication, as the evidence from trials was not strong enough due to the quantity of missing data due to patient withdrawals."

Gamification to increase patient retention

> "Gamification involves the use of video game elements to improve user experience and user engagement in non-games services and applications"



[2] J. Hamari, J. Koivisto and H. Sarsa, "Does gamification work? A literature review of empirical studies on gamification," HICSS '14 Proceedings of the 2014 47th Hawaii International Conference on System Sciences, pp 3025-3034, 2014.

Gamification to increase patient retention

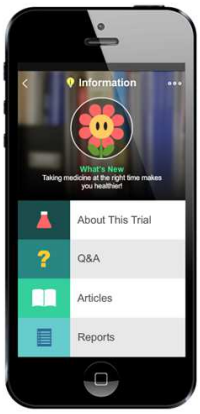
Motivation principles

1. Players with a strong achievement motive: achievement, success and progress
2. Players with a strong power motive: status, control and competition
3. Players with a strong affiliation motive: membership
4. Should provide immediate feedback in form of positive and negative reinforcement
5. Players are likely to be motivated if gamification offers rewards
6. Gamification should provide a clear and achievable goal, and the result of achieving the goal is clearly defined

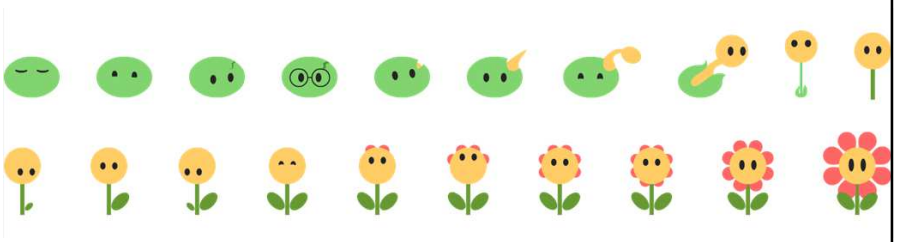
Most common motivational affordances

- Points
  - Positive reinforcements (4) and virtual rewards (5)
- Badges – visual representations of achievements
  - Fulfil need for success and status (1, 2), provide affiliation with others (3), goal setting (6)
- Leader-boards – information about individual success
  - Competition (2), team leader-boards for affiliation (3)

Gamification to increase patient retention



Trialsconnect.com



- Points, virtual rewards
- Driving behaviour to:
  - Read study information and updates
  - Complete assessments
  - Clinic attendance
- Link to physical rewards?

Gamification for other trial personas

Examples

Site staff

- Rapid subject recruitment
- Good patient retention
- Prompt data entry following patient visits
- Few data queries
- Fast Query turnaround
- Accurate and timely medication returns accounting

CRAs

- Rapid site on-boarding
- SDV performed to agreed timeframe
- Fast query resolution for responsible sites
- Fast issue resolution

Possible Application To Site Motivation
Badges And Virtual Awards

10 patients enrolled
by Bill Byrom, *Nottingham Hospital*, 18-May-2016
Well done and keep up the great work!

Data Expert
by Bill Byrom, *Nottingham Hospital*, 18-May-2016
Congratulations, your CRF data is now fully complete!

Silver Data Management Status
by Bill Byrom, *Nottingham Hospital*, 18-May-2016
Congratulations, on achieving subject data entered within 7 days of study visits this quarter

Possible Application To Site Motivation
Leader-boards

Patient Recruitment Leader-board

◀ May 2016 ▶

Rank	Site	Country	Total randomized	Randomized this month	Activation date	Previous rank
1	101 Bill Byrom Nottingham Hospital	GBR	17	4	04-Jan-16	1
2 ▲	313 Kurt Schwartz Mannheim Clinic	GER	15	4	04-Jan-16	3
3 ▼	108 John McKendrick Glasgow Infirmary	GBR	14	3	14-Jan-16	2
4 ▲	704 Henrik Larsson Uppsala Clinic	SWE	12	2	04-Jan-16	5

Possible Application To Site Motivation
Feedback

LinkedIn

Profile Strength

All-Star

Share your profile ▸

EDC

You just completed:

- 24 complete CRF pages
- 12 partial CRF pages
- 3 query responses

Data Management Strength

All-Star

Great work!

Translation To Tangible Rewards

- Performance bonus?
  - For the site staff as opposed to the institution
  - May not be possible based on company regulations
- Top sites recognised in trial publication authorship?
- Certified metrics and achievements to help attract new study business?

Current use of games and gamification in trials

3. Objective outcomes measurement

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Clinical outcomes measurement

AKILI Project:EVO

- Measures interference processing
  - Multi-tasking
- Application areas with diminished ability to multi-task / process distractions:
  - ADHD
    - Use of EVO as a treatment
    - Measure of ADHD interference processing
  - Alzheimer's
    - Biomarker for those at risk of AD.

Challenges: objective endpoints

Endpoints based on subjective ratings

Examples:

- Depression / anxiety symptoms and severity
- Mobility in stroke
- Pain
- Dermatology

Challenges:

- Sensitivity of endpoint
- Assessment time required
- Between-rater variability
- Perceptions of treatment may affect ratings.

Rehabilitation Medicine, University of Gothenburg

FUGL-MEYER ASSESSMENT **ID:**
UPPER EXTREMITY (FMA-UE) **Date:**
Assessment of sensorimotor function **Examiner:**

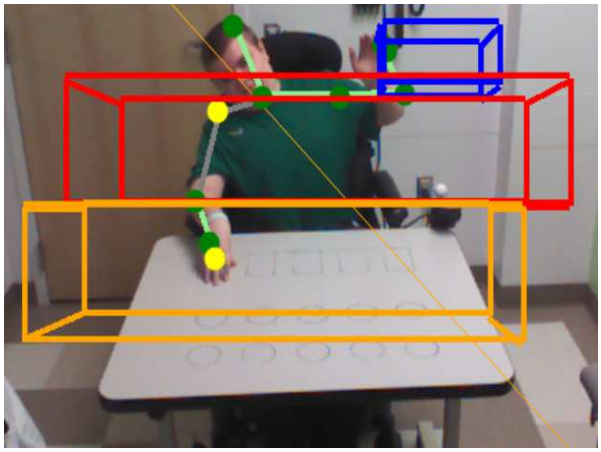
Fugl-Meyer AR, Jaasko L, Leyman I, Olsson S, Steglind S: The post-stroke hemiplegic patient. A method for evaluation of physical performance. Scand J Rehabil Med 1975, 7:13-31.

A. UPPER EXTREMITY, sitting position					
I. Reflex activity			**none**	**can be elicited**	
Flexors: biceps and finger flexors			0	2	
Extensors: triceps			0	2	
Subtotal I (max 4)					
II. Volitional movement within synergies, without gravitational help			**none**	**partial**	**full**
Flexor synergy: Hand from contralateral knee to ipsilateral ear. From extensor synergy (shoulder adduction/ internal rotation, elbow extension, forearm pronation) to flexor synergy (shoulder abduction/ external rotation, elbow flexion, forearm supination).	Shoulder	retraction	0	1	2
		elevation	0	1	2
		abduction (90°)	0	1	2
		external rotation	0	1	2
	Elbow	flexion	0	1	2
	Forearm	supination	0	1	2
Extensor synergy: Hand from ipsilateral ear to the contralateral knee	Shoulder	adduction/internal rotation	0	1	2
	Elbow	extension	0	1	2
	Forearm	pronation	0	1	2
Subtotal II (max 18)					

Fugl-Meyer assessment for Stroke recovery

Clinical outcomes measurement

ACTIVE-Seated
(Abilities Captured through Interactive Video-based Evaluation)

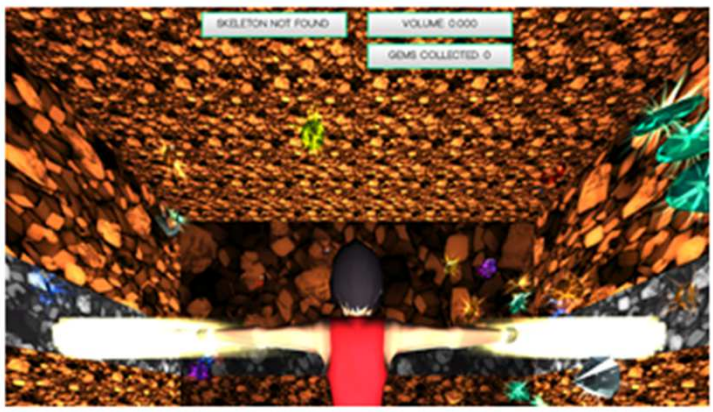


- Muscular Dystrophy patients
- Microsoft Kinect platform
- Functional reaching volume in six regions, left and right: overhead, side to side and forward
- Quantify upper extremity reaching ability on a continuous scale.

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.

Clinical outcomes measurement

- Game concept to measure arm reaching ability
- Cave – arm movements collect gems and remove spiders
- Quantifies upper extremity strength and function
  - Current tools fail to fully capture this.



Clinical outcomes measurement

Objective assessments using Microsoft Kinect

Kinect depth camera

- Detailed 3D video data capture

Microsoft SDK

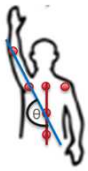
- Kinect for Windows
  - Adapter and SDK
- Out of the box algorithm and tools for
  - Skeletal tracking – up to 25 joints
  - Detailed 3D facial tracking

Current scientific work

- Walking, balance and gait assessment in stroke, MS and Parkinson's
- Upper extremity movement in Stroke and MS

ICON Product Innovation: proof of concept

- Shoulder range of motion measurement
- e.g. Shoulder abduction



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Clinical outcomes measurement

Considerations

- Game environments provide unique opportunities to capture endpoints that are difficult to measure in other ways
  - Aspects of cognitive function such as interference processing
  - Aspects of mobility and movement using motion-based platforms
- Compelling and engaging approaches to measuring clinical endpoints
- Some patient groups may find this approach more challenging than conventional assessments
  - Demographic of game players differs across countries and cultures
  - Clinical trials instruments must be acceptable across a broad range of patients
- Rehabilitation solutions might also measure endpoints in addition to delivering exercise regimens
- Need to show clinical relevance of measure for use in trial submissions.

Future direction

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Future direction and possibilities

- Growth in interactive learning approaches to patient information
- Drive to make trials more patient-centric
  - Gamified retention approaches
  - More engaging assessments
  - Greater ability to conduct assessments at home
- Drive engagement and motivation for other key stakeholders
  - Gamified approaches for site staff and monitors
- Further exploration of serious games to measure treatment-related effects
  - Developing sensitive objective outcomes where these don't currently exist

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Clinical Trials Re-spec: The Role of Games and Gamification in the Future of Clinical Trials

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