Title: A retrospective study on the acceptability, feasibility, and effectiveness of LoveYourBrain Yoga for people with traumatic brain injury and caregivers

Author: Kyla Z. Donnelly, Kim Baker, Ramsay Pierce, Amanda R. St. Ivany, Paul J. Barr & Martha L. Bruce

Journal: Disability and Rehabilitation

Volume: Published online: 02 Oct 2019

Doi: https://doi.org/10.1080/09638288.2019.1672109

Abstract

Purpose: To conduct a mixed methods, pre-post, retrospective study on the feasibility, acceptability, and effectiveness of the LoveYourBrain Yoga program.

Materials and Methods: People were eligible if they were a traumatic brain injury survivor or caregiver, age 15–70, ambulatory, and capable of gentle exercise and group discussion. We analyzed attendance, satisfaction, and mean differences in scores on Quality of Life After Brain Injury Overall scale (QOLIBRI-OS) and four TBI-QOL/Neuro-QOL scales. Content analysis explored perceptions of benefits and areas of improvement.

Results: 1563 people (82.0%) participated ≥1 class in 156 programs across 18 states and 3 Canadian provinces. Mean satisfaction was 9.3 out of 10 (SD 1.0). Mixed effects linear regression found significant improvements in QOLIBRI-OS (B 9.70, 95% CI: 8.51, 10.90), Resilience (B 1.30, 95% CI: 0.60, 2.06), Positive Affect and Well-being (B 1.49, 95% CI: 1.14, 1.84), and Cognition (B 1.48, 95% CI: 0.78, 2.18) among traumatic brain injury survivors (n = 705). No improvement was found in Emotional and Behavioral Dysregulation, however, content analysis revealed better ability to regulate anxiety, anger, stress, and impulsivity. Caregivers perceived improvements in physical and psychological health.

Conclusions: LoveYourBrain Yoga is feasible and acceptable and may be an effective mode of community-based rehabilitation.

Database

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Abstract

Introduction: Calcitonin Gene-Related Peptide (CGRP) plays a crucial role in migraine pathophysiology. A novel specific treatment strategy for the prevention of migraine incorporates monoclonal antibodies (mAbs) against CGRP and its canonical receptor. Eptinezumab, fremanezumab and galcanezumab block CGRP mediated effects by binding to the peptide, while erenumab blocks the CGRP receptor.

Areas covered: Following a brief overview of pharmacological characteristics, we will review phase III trials for the use of CGRP mAbs in the prevention of episodic and chronic migraine.

Expert opinion: All four CGRP mAbs demonstrated an excellent safety, tolerability and efficacy profile in migraine patients. Across all trials mAbs showed superior efficacy for the reduction of monthly migraine days compared to placebo with a net benefit of 2.8 days. Neither cardiovascular nor immunological safety concerns have emerged from clinical trials. Fremanezumab, galcanezumab, and erenumab are approved in the USA and Europe. Based on trial data there is no reason why these mAbs should not become first line therapies in future. For now, we advocate for the use of mAbs in migraine prevention for patients who failed a minimum of two standard oral treatments based on the novelty and costs of this approach. mAbs are also effective in patients with medication overuse and with comorbid depression or anxiety disorders. Taken together, mAbs are likely to usher in a new era in migraine prevention and provide significant value to patients.
Abstract

Introduction: Obesity is a very common public health problem worldwide. However, there is a lack of effective therapies. Only a small portion of patients with morbid obesity are accepting bariatric surgery as the last option due to the risks associated with invasive therapy.

Areas covered: In this paper, we review an emerging weight loss treatment: gastric electrical stimulation (GES). The feasibility of GES as a potential therapy for obesity is introduced. Methodologies and parameters of GES are presented. Several GES methods for treating obesity and their effects on food intake and body weight are presented. Possible mechanisms involved in the anti-obesity effect of GES are discussed. Finally, our comments on the potential of GES for obesity and expectations for future development of the GES therapy are provided. The PubMed central database was searched from inception to May 2019. The literature search used the following terms: “Gastric electrical stimulation” combined with “obesity” and “Implantable gastric stimulation” and “pharmaceutical therapy” and “bariatric surgery”.

Expert opinion: There is a potential to use GES for treating obesity. However, more efforts are needed to develop appropriate stimulation devices and to design an adequate therapy for treating obesity in humans.
Abstract

Introduction: Pancreatic ductal adenocarcinoma (PDAC) is a disease of high lethality. Invasive tissue biopsies of primary or metastatic lesions remain the gold standard for diagnosis, but repeated sampling is infeasible. Noninvasive liquid biopsies offer new opportunities for early diagnosis for high-risk cohorts, and for the longitudinal analysis of tumor evolution and progression in patients on therapy. Liquid biopsies can capture tumor-associated components, such as circulating tumor DNA (ctDNA), extracellular vesicles (EVs), and circulating tumor cells (CTCs), each of which provides genomic and molecular information about the underlying PDAC that can potentially inform clinical decisions.

Areas covered: Here, we reviewed current knowledge and recent technological advances regarding liquid biopsy in PDAC and mention the pitfalls and benefits in each methodology. We also discuss clinical correlative studies for diagnosis and prognosis in PDAC.

Expert opinion: In pancreatic cancer where tissue samples are limited and repeated tissue biopsies are mostly invasive and infeasible, liquid biopsies opened a new window for tumor diagnosis, molecular stratification, and treatment monitoring. While none of the isolation and analysis methods have gained widespread clinical acceptance, it is imperative that the advantages and limitations of each platform for isolation and analysis of tumor associated components are taken into consideration.
Abstract

Protein drugs present specific challenges to the maintenance of long-term stability, which can be accomplished by altering parameters of obtention, purification, molecule structure and formulation. As we believe, commercial formulations are undervalued; therefore, this review focuses on screening, categorising and discussing all formulations of protein drugs approved and not withdrawn by regulatory agencies from United States, Canada and Europe until mid-2018. Peptides (<50 amino acids) were not included to allow a more precise evaluation of choices for larger molecules. We extracted data from the DrugBank database, cross-checked it with the FDA purple book and supplemented it with patient information leaflets and papers. We further classified and discussed the entries according to protein function, drug delivery, route of administration and types of excipient (freeze-dried forms). In addition, alternative choices of excipients were discussed. Experimental work included here relates to targeting strategies with verified pharmacokinetics or in vivo effectiveness to identify physiologically relevant options. Although no single rule can be set for efficient protein formulation, our data help to better understand and optimise the choice for excipients and pharmaceutical dosage forms. For more information, see the Supplemental Data.
The current trend for clinical pharmacology is toward more complex studies (e.g., umbrella protocols covering single and multiple ascending doses, food effect, metabolism pathways), requiring many decisions to be made during their conduct. This article discusses guidance of such early clinical studies by modeling and simulation. The ability to make use of all available information each time new data become available during the study requires the modeling scientist to be unblinded. This must of course not jeopardize the blinding of the clinical team, and this article discusses how unblinding can be prevented. Although modeling and simulation are established for guidance of the drug development process overall, they are not frequently used for guidance on a small scale, that is, during studies with the largest uncertainty, the first-in-human studies. Application of a quantitative model backbone makes early clinical drug development a more efficient process and provides additional safety for healthy subjects and patients. Real clinical impact is illustrated by 3 case studies that show different contributions from unblinded modeling: dose escalation based on safety data, modeling and predicting with explicit incorporation of in vitro data, and dose escalation supported by unblinded analysis of adverse event data, which resulted in new insights of the clinical team without being unblinded and made it possible to proceed with dose escalation and to extend the study with an up-titration group.
Abstract

The development of efficient and repeatable protocols for biobanking and prolonged storage of cancer stem cells (CSCs), with minimum alterations in biological function, is valuable and desired, particularly for retrospective analysis and clinical applications. In particular, data regarding the effect of cryopreservation on CSCs's functional features is scarce. In this regard, few studies have been shown that 3D spheroid structures, which enriched for CSCs, can keep their biological phenotype and genetic profiles. Here, for the first time, we present data on cryopreservation of CT-26 colonospheres, with the focus on essential stem cell-like properties after thawing. Tumor biopsy-derived colonospheres were frozen in standard freezing media (90% fetal bovine serum + 10% dimethyl sulfoxide) and stored in liquid nitrogen for 10 months. Then, cryopreservation effect on preservation of CSCs-related features was verified using real-time polymerase chain reaction for evaluation of stemness genes and flow cytometry for the putative colorectal CSC surface biomarkers. The self-renewal capacity of thawed spheroids was also compared with their fresh counterparts using serial formation assay. Finally, tumorigenic capacity of both groups was evaluated in immunocompetence mouse model. Our data indicated that postthawed colonospheres had high viability without drastic alteration in biological and structural features and maintained self-renewal potential after sequential passages. Real-time analysis showed that both fresh and frozen colonospheres displayed similar expression pattern for key stemness genes: SOX2 and OCT4. Cryopreserved spheroids expressed CD133, CD166, and DCLK1 CSCs surface biomarkers at elevated levels when compared with parental as non-cryopreserved counterparts. Our electron scanning microscopy micrographs clearly demonstrated that postthawed colonospheres retain their integrity and cell surface morphology and characteristics. We also found that both fresh and frozen spheroids were equally tumorigenic. This study represented an effective strategy for reliable storage of intact CT-26 colonospheres; this can provide researchers with a functionally reliable repository of murine colorectal CSCs for their future CSCs projects.
Abstract

Case Report Editor Note: This column typically reviews cases brought forward by critical care transport clinicians from around the country. However, this month's case is a little different. It chronicles the experience of one of our providers as he identifies his own cardiac condition. The relevance of this case lies in the fact that occasionally our own staff encounter their own medical issue, and it is educational for out-of-hospital providers to not only review cases of patients for whom we provide care but also, just as importantly, how we work with medical care when critical care transport specialists are the patients themselves.
Exploring Cognitively Loaded Physical Activity Compared With Control to Improve Global Cognitive Function in Older Community-Dwelling Adults With Mild Cognitive Impairment: Systematic Review With Meta-Analysis

Author: Kristina Zawaly, Richard Fortier, Stephen Buetow, Lynette Tippett, Ngaire Kerse

Journal: American Journal of Lifestyle Medicine

Volume: First Published September 27, 2019

Doi: https://doi.org/10.1177/1559827619876887

Abstract

Objective. A systematic review with a meta-analysis explored effects of cognitively loaded physical activity interventions on global cognition in community-dwelling older adults (≥65 years of age) experiencing mild cognitive impairment (MCI), compared to any control. Methods. A literature search was conducted in 4 databases (MEDLINE [OvidSP], PubMed, CINAHL, and the Cochrane Central Register of Controlled Trials [Wiley]) from inception until January 30, 2018. The meta-analysis was conducted with Review Manager 5.3. Results. Six randomized controlled trials (RCTs) with 547 participants were identified. The interventions ranged from 4 to 52 weeks. Baseline and initial follow-up assessments were used. The primary pooled analysis of all RCTs demonstrated a nonsignificant trivial effect (standardized mean difference [SMD] 0.07, 95% confidence interval [CI] −0.44 to 0.58) favoring the intervention. In pooled subanalysis of 4 RCTs (n = 405) using the same global cognition measure (Mini-Mental State Examination) and duration of intervention >12 weeks, the intervention group achieved a small but significant improvement for global cognition (SMD 0.45, 95% CI 0.14 to 0.75). Conclusion. When all the RCTs were pooled, the effect of cognitively loaded physical activity intervention on global cognitive function in older adults with MCI remained unclear. The subgroup analysis provides translation evidence for future RCT study designs.
Abstract

OBJECTIVE. The purpose of this article is to present a targeted literature review describing the current state of radiology initiatives in support of shared decision making and gaps that offer opportunities for innovation and improvement.

CONCLUSION. Breaking down the shared decision-making process into its four major components (access to information, comprehension of the information, appraisal of the information, application of knowledge in care decisions) reveals the role of radiologists in the decision-making process and opportunities for expanding this role.

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