



Setting up aTMS Clinic

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Contents

- Safety and training of personnel
 - Equipment
 - Certification
 - Evaluation and Consent
 - Treatment Protocol
 - Assessment
 - Maintenance
 - Cost/Billing
 - Future Developments
- Starting program
- Managing patients
- Long term plans

Setting up a TMS treatment Program

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graph TD; A([Setting up a TMS treatment Program]) --> B[Safety]; A --> C[Training]; A --> D[Equipment]; A --> E[Certification];
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Safety.

1. Protocols for TMS and management of seizure
2. Safety equipment
3. Patient Screening

Training.

1. Program Director
2. Psychiatrist
3. TMS Technician

Equipment.

1. Rapid stimulator
2. Safety equipment
3. Supplies

Certification

1. FDA-cleared device
2. Local safety committee/ IRB
3. Informed consent



Personnel

- Clinicians (Neurology / Psychiatry)
- Administrative support
 - Scheduling
 - Providing information to prospective patients
 - Data collection
- Technicians
 - TMS trained
 - Basic Life Support
 - Patient interaction

Safety

- Patient selection- seizure risk
- TMS protocol- 10-20hz vs. 1hz
- Safety equipment
 - In hospital
 - Clinic/outpatient setting
- Training of staff in management of seizures



Equipment

- TMS machine
 - Approved device options
 - Cooled coil
 - We use both neuronetics and magstim
- Earplugs and swimming cap
- Safety equipment
 - Tylenol
 - To treat a seizure
 - Emergency medical services

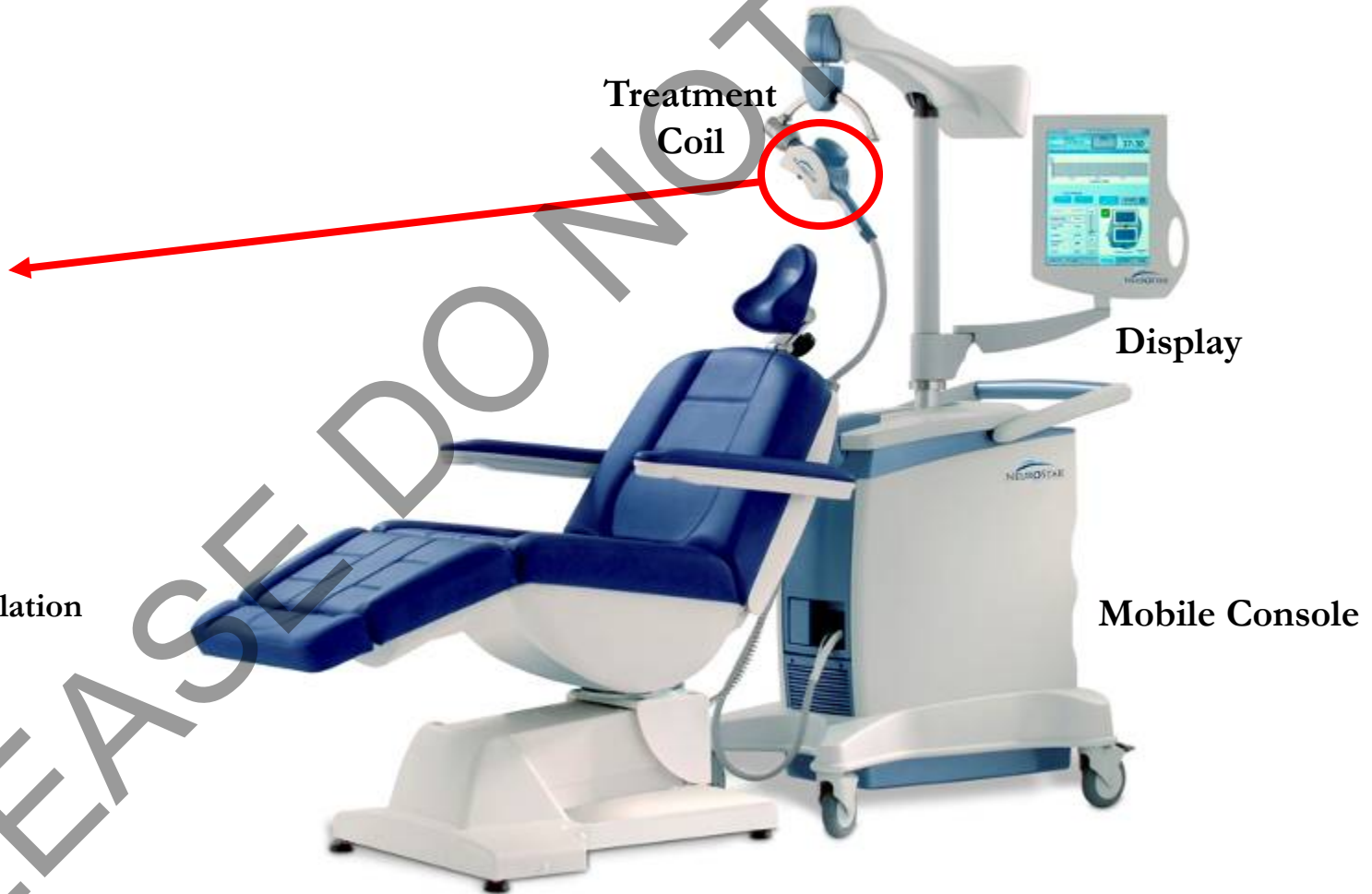


Neurostar TMS Therapy



**Senstar™
Treatment Link**

- Contact sensing
- Dose confirmation
- Surface field cancellation
- Hygiene barrier

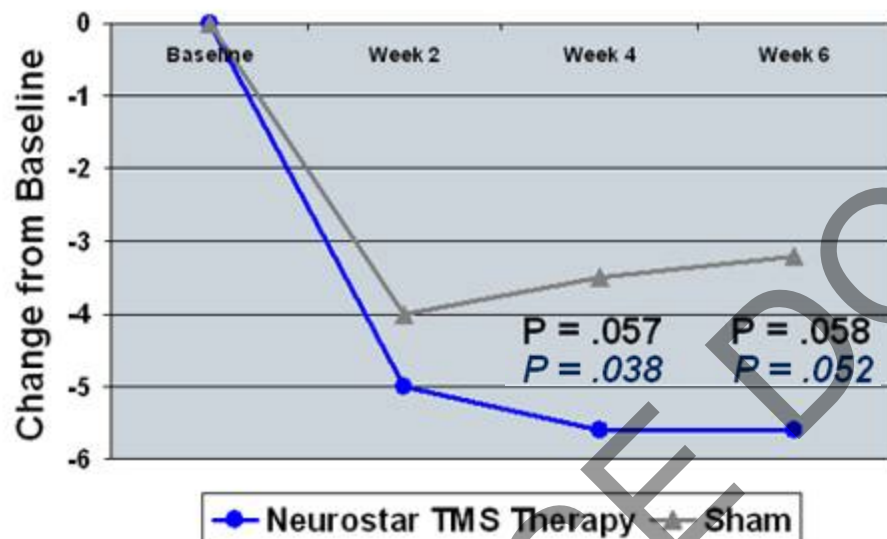


Effect on Continuous Outcomes

MADRS and HAMD24 Rating Scales

MADRS Total Score

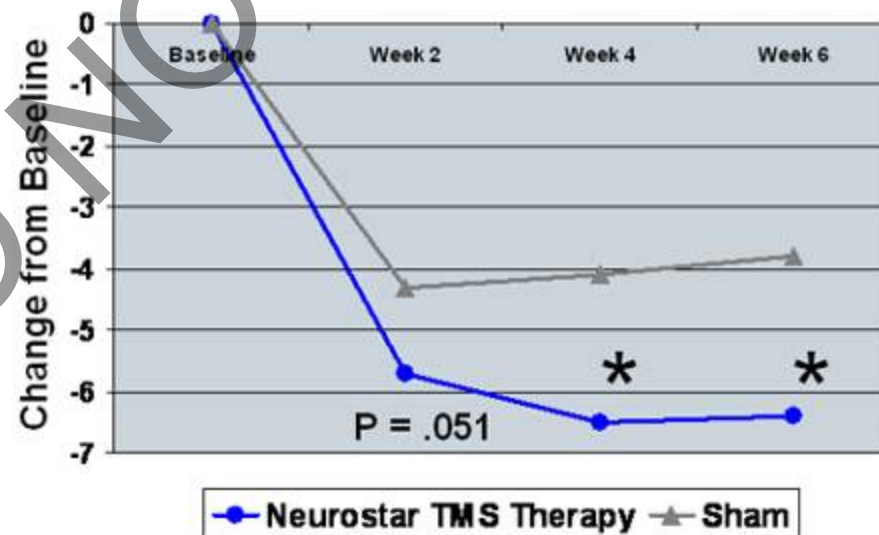
Baseline to Endpoint Change



...P-Values with correction for baseline imbalance in Total MADRS Score
 [N=6 patients censored w/Total MADRS < 20 at baseline]

HAMD24 Total Score

Baseline to Endpoint Change



* $P < 0.05$, LOCF analysis

TMS Timeline

1984

1987

1996

2007

2008

2012

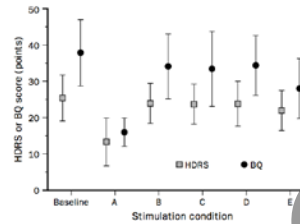
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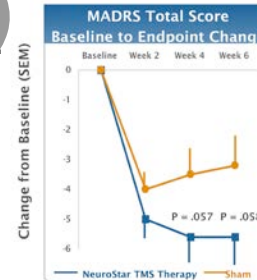
Anthony Barker
Single Pulse TMS



Cadwell
Repetitive TMS
(rTMS)



Pascual-Leone, et. al.
George, et. al.
rTMS for depression



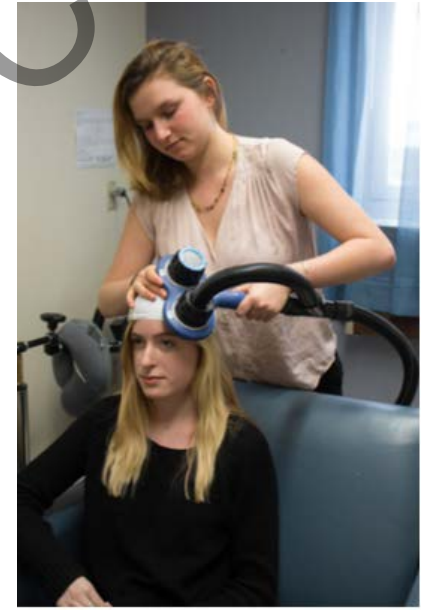
Neuronetics Phase III
trial of rTMS for
Medication-resistant
depression

FDA
clearance

NHIC
Medicare
Approval
(MA, NH, VT
and RI)

Coverage from
Most insurers,
Brainsway
Clearance

Devices and Financial Models



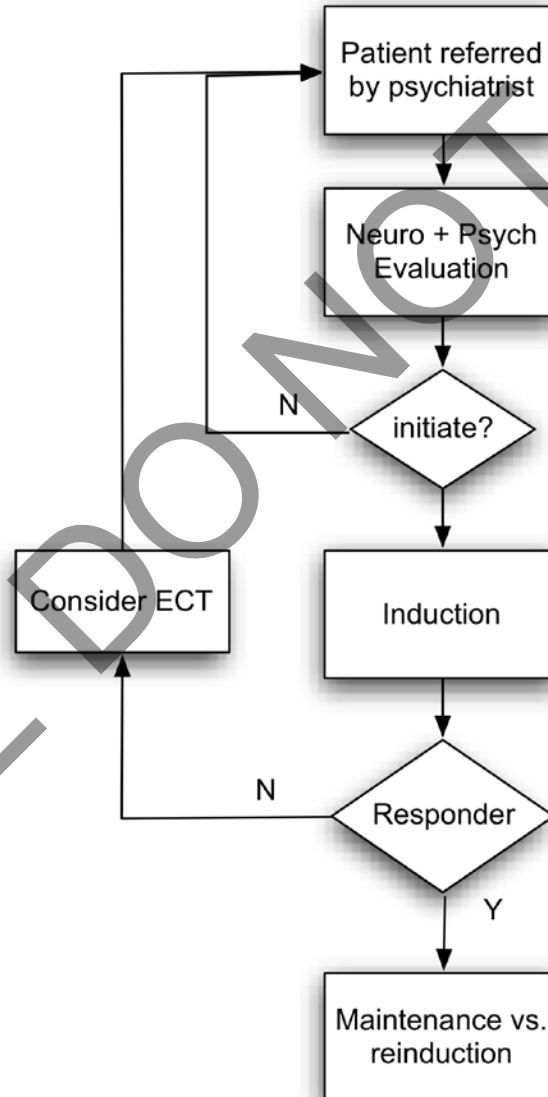
Manuf.	Neuronetics	Brainsway	Magstim
FDA cleared for depression:	Yes	Yes	Yes
Purchase model	Mixed (Purchase + starstim)	Rental	Purchase



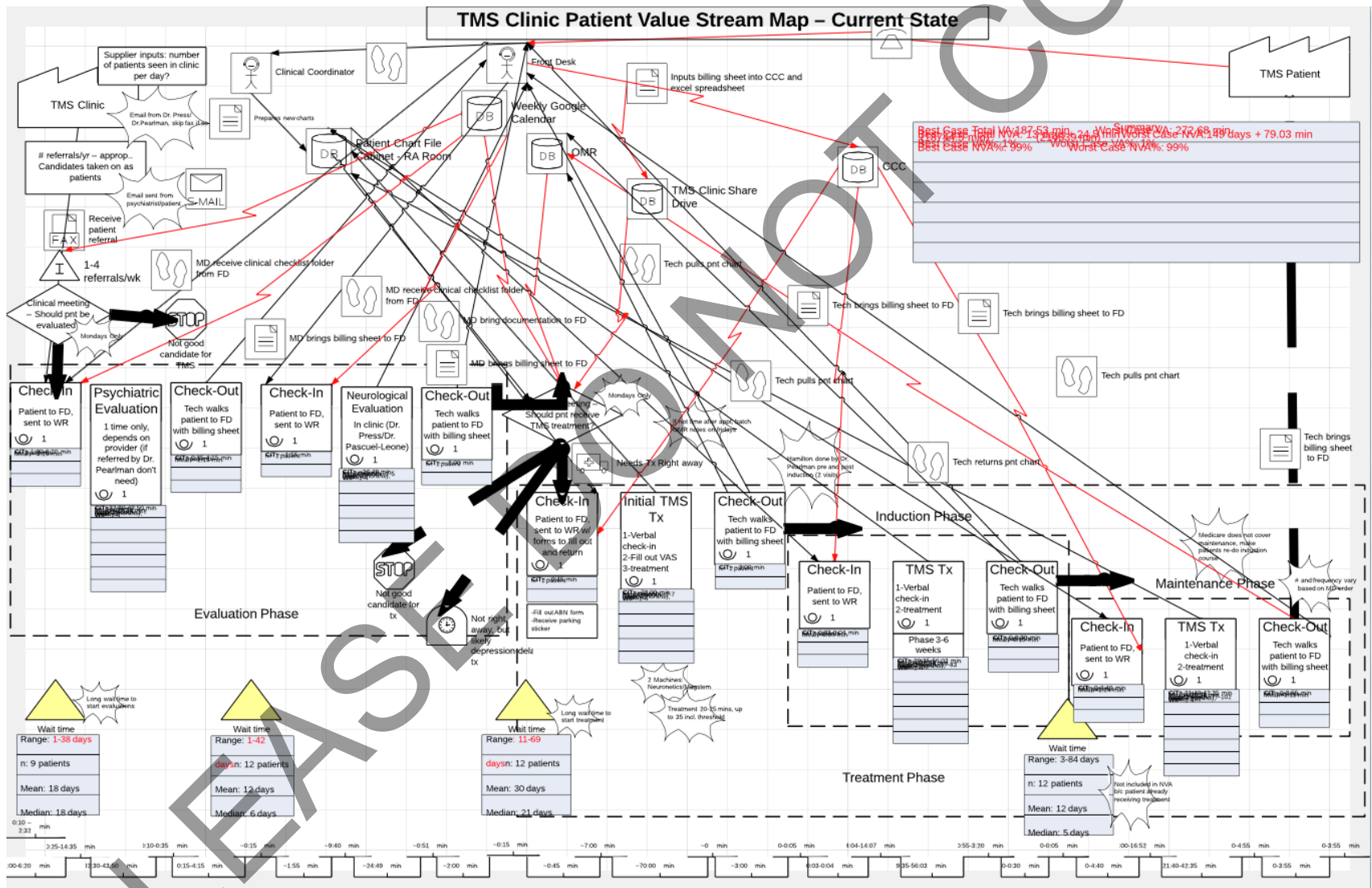
Initial Evaluation

- Referral from treating psychiatrist
- Neurology
 - Contraindications
 - Effect of medication on TMS
- Psychiatry
 - Caution if: Psychotic depression, bipolar, personality disorders
 - At least one adequate trial of antidepressant medication

How we saw it....



How Lean Saw it...





Consent

- Local ethical/safety committee (not IRB!)
- Discussion of on-label vs. off-label treatment
- Explanation of side-effects
 - Seizure
 - Headache
 - Tinnitus/hearing loss



BIDMC Treatment Protocol

Site	Hemisphere	Frequency	Duration	Wait time	Repetitions
Neuronetics	Left DLPFC (120% MT)	10 Hz	4 seconds	26 seconds	75 (3000 pulses)
DLPFC	Right (110% MT)	1 Hz	1600 seconds	N/A	1 (1600 pulses)
Brainsway	Left DLPFC (120% MT)	18 Hz	2 seconds	20 seconds	55 (1980 pulses)
DLPFC (5.5 cm)	Left DLPFC (110% MT)	20 Hz	2 seconds	28 seconds	40 (1600 pulses)



Initiation Phase

- Treatments daily (excluding weekends)
- Mood assessed weekly
- Minimum 2 weeks
- Maximum 6 weeks
- Taper?

Alternatives being investigated

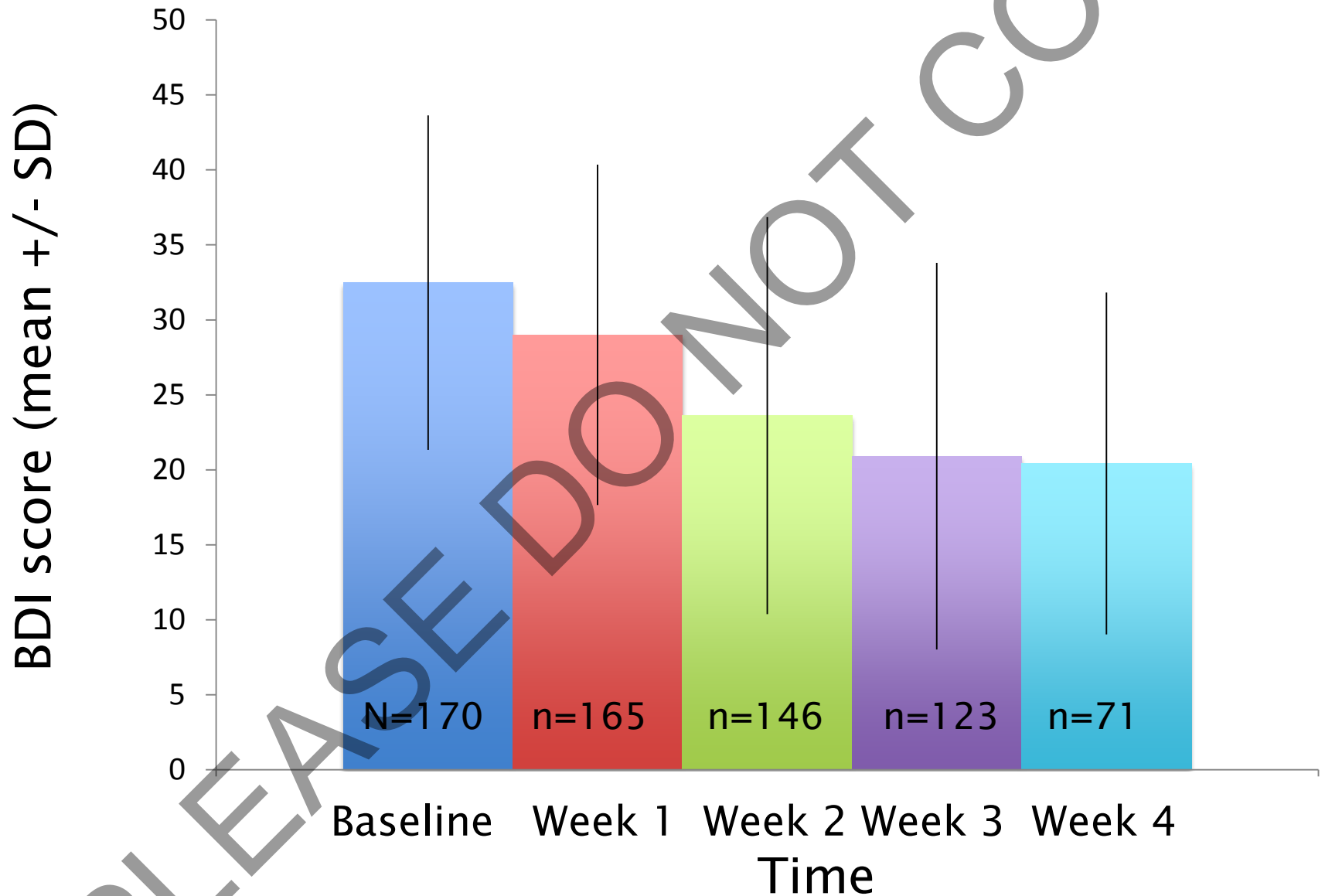
- Choosing protocol on clinical parameters (anxiety, risk of mania/sz)
- Using MRI guidance for targeting
- Using anatomical MRI to help with intensity of stimulation (particularly in elderly)
- Others: mood induction, more than one session/day



Assessment tools

- Beck, Hamilton, Visual-analogue scale
- Target symptoms
- Clinician evaluation of patient
- Other sources of information (e.g. family, referring psychiatrist)
- Side effects questionnaire
- Weekly meeting of all staff to discuss progress

Overall Results from Clinical Program





Maintenance Phase

- **Minimal evidence** (absence of evidence, not evidence of absence)
- **Relapse prevention**
 - Start with weekly treatment
 - Gradually space out sessions
- **“Watchful Waiting”/reinduction**
 - Patient presents when feeling worse



Maintenance:

Initial Course

Maint 1 week

Q 2 weeks

Q 3-4 weeks

Reinduction:

Initial Course

Taper 2 to 1x/wk

Stop

if relapse 2-3/wk

Taper



Cost

- Medicare coverage in 4 of 12 districts
- Insurance Coverage
- \$400-\$500 initial session with MT, then \$350-\$400 non-MT session
- How frequently to measure MT?
- Helping with reimbursement, creating fund for low income patients

Reimbursement for TMS

- Currently its approved by most payers (Medicare, BC/BS, Tufts)
- Each carrier has slightly different criteria
- New devices are coming on line

Percent Improvement (NIBS – Sham)

60
50
40
30
20
10
0

Nontargeted

Targ

Epilepsy

Motor stroke
tDCS

Cathodal

Bi
Anodal

Motor stroke
rTMS

Ipsi

Contra

Parkinsons

M1

Non M1

M1

Pain tDCS

Prefrontal

Pain rTMS

Tinnitus

Future Developments

- Targeting (use of structural MRI's and fMRI's for intensity and targeting?)
- Interaction of rTMS with medications
- Predictors of response
- Monitoring response biologically
- Other indications (pain, seizures, stroke recovery, Parkinson's disease)

Questions?

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