Feasible delivery of intensive speech treatment: Telepractice and LSVT® Companion™

2011 Convention of the American, Speech, language and hearing association, San Diego, California

Cynthia Fox, Lorraine Ramig, Angela Halpern, and David H. McFarland
LSVT Global Inc.
It’s a “stunning” time to be in Rehabilitation in PD
To provide symptomatic relief; improve function

Pharmacological (L-dopa)

Neurosurgical (DBS-STN)

Voice and Body Exercise

Zigmond et al, 2009
Video Example:
59 year old female
2.5 years post-diagnosis
On-meds pre and post video

Pre/post LSVT
(Lee Silverman Voice Treatment)
Intensive physical exercise of speech mechanism
The Need

1987

No effective speech treatment for PD

Nearly 90% of the 4-6 million individuals with PD worldwide have a speech problem

4% receive speech treatment
(Mutch et al, 1986; Hartelius & Sveensson, 1994)
LSVT LOUD

Standardized, research-based, specific protocol
Delivered by LSVT Certified Clinician
Adheres to principles of neuroplasticity (Kleim & Jones, 2008)

**SPECIFICITY - SINGLE FOCUS**
Amplitude - Think LOUD! – Retrain NORMAL USE
Challenges the impaired system – PD-specific approach

**INTENSITY**
16 1-hour individual sessions; 4 days/week; High Effort

**REPETITION**
Daily Tasks – Over learned

**COMPLEXITY/CHALLENGING**
Progressive Hierarchies
Promote continuous use in everyday activities

**SALIENCE**
Feedback and Motivation; Empower/Reinforce/Instruct
NIH Funding – over 20 years and 8 million dollars

**Phase I, II**

1987-89: Initial invention; Pilot data (Scottsdale)
1989-91: Office of Education OE-NIDRR

**Phase III**

1991-94: OE-NIDRR
1990-95: NIH funded RCT Efficacy
1995-00: NIH funded EMG, Kinematics
2002-07: NIH funded RCT Spread of effects
2007-12: NIH funded RCT, imaging
ALL EFFICACY DATA BASED ON LSVT 4x WEEK FOR 4 WEEKS (GOLD STANDARD)

Intensive treatment is challenge to scaling up LSVT
Barriers to use

• We realize that effective, intensive speech treatment LSVT® LOUD is not accessible to the majority of people with Parkinson disease (PD)
  – Geographic barriers
  – Financial constrains
  – Inadequate numbers of speech clinicians all limit utilization
Need for solutions

- Growing interest in “in home” delivery of speech treatment protocols via telepractice
  - Newly created ASHA special interest division (SID 18)
- Speech/language intervention is often well tailored for distance
Need for solutions

• LSVT LOUD is ideal for these applications
  – Standardized 16 session protocol
  – Well-defined outcome measures
    • Sound Pressure Level (SPL)
    • Fundamental frequency (F0)
    • Duration
Our solution

• Technology supported delivery of LSVT LOUD through two platforms
  – LSVT eLOUD (our telepractice application)
  – LSVT Companion
  – Combined telepractice with LSVT Companion
What is telepractice?

• “The use of telecommunications technology for medical diagnostic, monitoring, and therapeutic purposes when distance separates the users.”

   - Agency for Healthcare Research and Quality (2001)
ASHA Telepractice Statement

• The use of telepractice **does not** remove any existing responsibilities in delivering services, including
  – adherence to the Code of Ethics, Scope of Practice, state and federal laws (e.g., licensure, HIPAA, etc.), and ASHA policy documents on professional practices.

• Therefore, the quality of services delivered via telepractice must be consistent with the quality of services delivered face-to-face.
Three published feasibility studies (Howell, Tripoliti & Pring, 2009; Theodorus et al.; 2006 and Tindall et al., 2008) have delivered LSVT LOUD using telepractice and offer initial support for positive treatment outcomes, client and clinician satisfaction, and cost effectiveness of this mode of delivery.
Options: Locations

• Clinician:
  – institutional clinic
  – private practice
  – home office

• Patient:
  – home
  – office
  – senior center
  – nursing home
Options: Equipment

• Clinician:
  – Institutional telehealth system
  – Commercially available systems

• Patient:
  – Match connectivity with this system
Options: Implementation

• LSVT LOUD face-to-face assessment and treatment
  – LSVT eLOUD follow-up

• LSVT LOUD face-to-face assessment and treatment
  – Some live tx sessions alternate with LSVT eLOUD, follow-up with LSVT eLOUD

• LSVT LOUD assessment, treatment, and follow-up delivered by LSVT eLOUD
Unique Considerations

• Confidentiality
• Reimbursement
• Licensure
Financial implications

• The live delivery mode required 51 hours for 16 visits (travel and therapy time), $953.00 on fuel/mileage expenses and $269.00 for other expenses (e.g. food).

• Telepractice delivery option required 16 hours of time (therapy, no travel), and no additional costs for fuel/mileage or other expenses.

» Tindall et al, 2008
Inadequate # of clinicians

• Just in terms of clinician time and accessibility:

• One clinician can treat a maximum of 7 patients in a month with LSVT® LOUD
  – (84/year max; 4-6 million individuals with PD………
  – We would need 90,000 years of clinician time!
LSVT Companion

• Originally developed by
  – Matos, Ramig, Halpern, Bennett at University of Colorado – Boulder
  – Research funded by National Institutes of Health and Michael J Fox Foundation (Research study)
Development

• Additional development for commercialization (translational)
  – LSVT Global, Inc. (Halpern, Ramig, McFarland and Fox)
  – Magpie Telecom Insiders
  – Lucinda Sanders
LSVT Companion

• Current system includes
  – Downloadable and interactive software
  – Proprietary SPL calibrated microphone (put patent here?)
  – Other treatment collaterals

• Minimum system requirements
  – Microsoft® Compatible 1GHz Pentium Class Computer with 512 Mb RAM, running Windows® 2000 SP4, XP SP2, or VISTA operating systems
Select a Client: Jones, Sam 04/12/1944

Options:
- Display Data
- Play Audio

- Client Information
- Collect Tx Data
- Initial Assessment
- Editor
- Set Goals
- Set Password

Start Client Exercise

Exit
Key features

• Automatically obtains calibrated SPL, F0 and duration for both LSVT assessment and treatment
  – No more SPL meter, F0 tuner and pencil and paper!

• Functions as a standalone software program
  – Allowing individuals with PD to progress through an entire treatment session
Welcome, Sam Smith

Options:
- Display Data
- Play Audio

Start Exercises
Exit
Potential Uses

• Pre/Post Assessment
• Within treatment data collection
• Client exercises with you in clinic
  – Half session with LSVT-C, half with clinician
  – Practice station post-LSVT for maintenance
• Client independent exercises
  – Homework practice during LSVT
  – Independent treatment session at home (Halpern et al)
  – Continued practice after the end of LSVT therapy
NIH R21

• 50% of LSVT sessions at home on PDA
16 individuals with PD

• Ss were screened prior to the study:
  – Possess necessary cognitive, visual and motor skills?
    - Mini-Mental State Exam
    - Beck depression Inventory
    - Dysphonia Severity Index
    - Voice/Speech Severity Rating,
    - Hearing Screening
    - Oral mechanism exam
    - LSVTC device usability test
    - Otolaryngology exam

Six of the 16 subjects had tremor in their dominant hand,
3 had apparent upper body dyskinesias.
Pre, Post, 6 month dB SPL (p< 0.001)

Changes consistent with those reported in previously published data Halpern et al, in prep
Combined Modalities

- LSVT Companion and Telepractice delivery of LSVT LOUD
- Standardized and valid online data collection during telepractice delivery of LSVT LOUD in two ways
  - the clinician using two computers: one for the videoconference aspect of the treatment session and one for LSVT Companion data collection
Second method

- LSVT Companion Home Edition installed on client’s computer.
- Clinician uses remote access software to control the client’s computer and operate the Companion during a treatment session.
- This allows for absolute, calibrated SPL, frequency and duration data
Data on eLOUD and Companion

• Data Transmission Rating Scale: Results Summary
  – Part 1
  • Delay Acceptability: Subjects responded that the delay was between 94 and 100% acceptable (scores of 94%, 97%, 100%).

• Communication Difficulty: Subjects responded that there was between 0 and 13% difficulty (scores of 0%, 4%, 13%).
• Part 2
  – All three participants rated the connection quality with a score of “excellent”.

  – Part 3
  • Two out of three subjects rated the ease of transmission as requiring minor effort. One subject rated no effort was necessary.
Putting it all together

• Explained the use of telepractice for speech treatment and published data supporting outcomes for telepractice delivery of LSVT LOUD

• We have summarized the data collected by the LSVT Companion and features of the program
Putting it together continued

• Described the treatment outcome data when the LSVT Companion was used for part of the LSVT LOUD treatment sessions

• Described methods for using the Companion for valid data collection during telepractice delivery of LSVT LOUD
Call to action

• Use these tools, your clinical expertise and your passion to improve the communication abilities of your patients and increase accessibility to LSVT LOUD!
QUESTIONS

WWW.LSVTGLOBAL.COM
Disclosures

Lorraine Ramig receives lecture honorarium and has ownership interest in LSVT Global, Inc. She is in full compliance with Federal Statute (42 C.F.R. Part 50.Subpart F) and the University of Colorado Policies on Conflict of Interest and Commitment.

STATEMENT ON DISCLOSURE AND CONFLICT: Any conflict of interest has fully disclosed and the conflict of interest management plan has been approved by the Office of Conflict of Interest and Commitment at the University of Colorado, Boulder.
PLAN

- Our PATH
- Problem
- Research
- Outcome
- Product
- Company
- Progress
- Perspectives
1988...The problem

• 89% of 6 million people with Parkinson disease worldwide have disordered speech that negatively impacts quality of life

• Medical interventions do not significantly improve speech

• “if I have no voice, I have no life”- Natalie
We have been chipping away for twenty years...

Today LSVT® LOUD has Level 1 evidence for speech treatment for Parkinson disease, is being delivered in over 50 countries and has been endorsed by the National Institute of Clinical Excellence (NICE) in Great Britain.
Daily tasks
First half of treatment session
Rescale amplitude of motor output through CORE Loud

- Sustained “ah” (minimum 15 reps)
- High/Low “ah” (minimum 15 reps)
- Functional phrases (minimum 50 reps)

Hierarchical speech tasks
Second half of session
Train amplitude from CORE exercises into in context specific and variable speaking activities

- Week 1 – words, phrases
- Week 2 – sentences
- Week 3 – reading
- Week 4 - conversation

The Product
Standardized research based behavioral treatment protocol
Lee Silverman Voice Treatment : LSVT
**The Product**

<table>
<thead>
<tr>
<th><strong>LSVT LOUD</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intensity:</strong> STANDARDIZED</td>
</tr>
<tr>
<td><strong>Dosage:</strong> 4 days/week for 4 weeks (16 sessions in one month)</td>
</tr>
<tr>
<td><strong>Repetitions:</strong> Minimum 15 repetitions/task</td>
</tr>
<tr>
<td><strong>Effort:</strong> push for max patient-perceived effort each day (8 or 9 on scale of 1-10 with 10 being the most)</td>
</tr>
<tr>
<td><strong>Simple Focus:</strong> LOUD</td>
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<tr>
<td>Increased movement amplitude directed predominately to respiratory/laryngeal systems</td>
</tr>
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</table>

**Daily Tasks:** first half of the treatment session (25 minutes)

- **Task 1:** Maximum sustained movements
  - 15 reps: sustain “ah” in good quality, Loud voice as long as possible
- **Task 2:** Directional movements
  - 15 reps each: say “ah” in Loud good quality voice going high in pitch; 15 reps each: say “ah” in Loud good quality voice going low in pitch
- **Task 3:** Functional movements
  - Patient self-identifies 10 phrases or sentences he/she says daily in functional living (e.g., “Good morning”) 5 reps of the list of 10 phrases. “Read phrases using same effort/loudness as you did during the long ‘ah’”

**Hierarchy:** second half of the treatment session (25 minutes)

- Designed to train rescaled amplitude/effort of movement achieved in CORE exercises from Daily Tasks into context specific and variable speaking activities
- Incorporate multiple repetitions with a focus on high effort (e.g., list of 20 phrases/sentences repeated 10 times for 200 repetitions)
- Tasks increase complexity across weeks (Words-phrases-sentences-reading-conversation) and can be tailored to each subject's goals and interests (e.g., golf vs. cooking)
- Tasks progress in difficulty by increasing duration (maintain LOUD for longer periods of time) amplitude (loudness - within normal limits), and complexity of tasks (dual processing, background noise and attentional distracters)

**Sensory Calibration**

**Treatment:** Focus attention on how it feels and sounds to talk LOUD

**Carryover activities:** start day one; daily assignments (treatment and non-treatment days); use loud voice in real life situations; difficulty of the assignment matches the level of the hierarchy where the person is working; make patient accountable and look for comments from patient that people in their daily living have said, such as, “I can hear you better”

**Homework practice:** start day one: daily assignments to practice at home (Daily tasks and hierarchy exercises); treatment days (one other time for 5-10 minutes); non-treatment days (two times for 10-15 minutes); homework book provided and patient made accountable
LSVT® treatments are specific, standardized, research-driven protocols that are copyrighted and patent-pending.

Only therapists who have completed a 12 hour training program can deliver LSVT® LOUD and LSVT® BIG treatment methodology and use LSVT trademarks associated with their therapy.

First Level 1 Evidence
Classic path

What if tech transfer does not want your product?

Product invented

Inventor discloses

Tech Transfer office evaluates commercial potential and may licenses IP to a Company

Company raises money for product development and translates to commercially viable product

IP is protected (e.g., Patent, Trademark, Copyright)

Product is successful and makes a positive impact
Real World
"Clinical Trenches"
Patient Populations

Valley of Death

“Ivory Tower”
Research Lab
Valley of death

To improve human health, scientific discoveries must be translated into practical applications.

-NIH
Our path

Product invented

Inventor discloses

Tech Transfer office evaluates commercial potential and may licenses IP to a Company

We developed a start-up company
LSVT Global EVOLUTION

Global Scalability
LSVT Global, LLC

Information Dissemination and Certification
LSVT Foundation, a 501c3 organization

Scientific Research Underlying Biobehavioral Treatments
National Center for Voice and Speech, over 8 million in NIH funding
We took this on because we were passionately committed to our VISION: increase patient accessibility to efficacious treatment to improve quality of life
Entrepreneurs’ Backgrounds

Dr. Cynthia Fox  Dr. David McFarland  Dr. Lorraine Ramig
KEY Product Fidelity: Train speech clinicians in standardized protocol to ensure fidelity of treatment

Implement technology to further increase accessibility
LSVT Global, Inc TODAY

- 6,000 speech clinicians trained in 60 countries
- Development of new products to increase treatment accessibility and maintain treatment fidelity (online training, software supported treatment)
- Development of new research-based treatments
Over 6,000 LSVT LOUD Certified Clinicians in nearly 50 countries
Over 1,000 LSVT BIG Certified Clinicians in 7 countries
LSVT® LOUD global standard for Speech Treatment for PD  (Pinto et al., 2004) NICE Great Britain

Maintain Treatment Fidelity:
Global Standardized Treatment
Standardized Training

Over 6,000 LSVT LOUD Certified Clinicians in nearly 50 countries
Over 1,500 LSVT BIG Certified Clinicians in 10 countries
LSVT Global, Inc. Products

- **Training**
  - In person training LSVT LOUD, LSVT BIG
  - Online LSVT LOUD training
  - Online Renewal
  - Online training modules

- **Treatment**
  - LSVT LOUD standard protocol
  - LSVT BIG standard protocol
  - LSVT Hybrid standard protocol
  - LSVT Companion software
  - LSVT eLOUD
  - LSVT Homework Helper
# LSVT Global Product Portfolio

<table>
<thead>
<tr>
<th>LSVT® Product</th>
<th>Description</th>
<th>Cost ($000)</th>
<th>Release</th>
<th>Billing</th>
<th>% of Sales*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current Portfolio</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSVT LOUD &amp; BIG Certification Workshops</td>
<td>Training of Speech and Physical Clinicians generated $434k of revenue in 2007</td>
<td>Available</td>
<td>Available</td>
<td>$550 Per clinician</td>
<td>8%</td>
</tr>
<tr>
<td>LSVT eLOUD</td>
<td>Webcam Training generated $17k of revenue in 2007</td>
<td>Available</td>
<td>Available</td>
<td>$1,700-3,400 Per patient</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Future Portfolio</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSVT eLOUD Companion Release 1</td>
<td>Interactive therapy stand alone software and microphone</td>
<td>$280</td>
<td>Q4 2008</td>
<td>$499/clinician $288/patient</td>
<td>86%</td>
</tr>
<tr>
<td>LSVT eLOUD Companion Release 2</td>
<td>Central data base for results, Web interface to access the data</td>
<td>$150</td>
<td>Q1 2009</td>
<td>$699/clinician $288/patient</td>
<td></td>
</tr>
<tr>
<td>LSVT eLOUD Companion Release 3</td>
<td>Full SaaS delivery model (Software as a Service)</td>
<td>$250</td>
<td>Q3 2009</td>
<td>$24-$22/month</td>
<td></td>
</tr>
<tr>
<td>LSVT Learning Management System</td>
<td>Online LOUD and BIG Certification Workshops</td>
<td>$160</td>
<td>Q4 2008</td>
<td>$580/clinician</td>
<td>4%</td>
</tr>
<tr>
<td>Video Development</td>
<td>Various</td>
<td>$65</td>
<td>Q3,4 2008</td>
<td></td>
<td>1%</td>
</tr>
<tr>
<td><strong>Total Product Investment</strong></td>
<td></td>
<td>$905</td>
<td></td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

* % of sales = over 5 years
# Parkinson disease Specific Product development

<table>
<thead>
<tr>
<th>Content</th>
<th>Delivery</th>
<th>Delivery Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>LSVT/LOUD</td>
<td>Done</td>
<td>Enhancement: LSVT-C data collection tool</td>
</tr>
<tr>
<td>LSVT-C</td>
<td>Done</td>
<td>Ready Enhancement: Data management reporting, and alerts Enhancement: Level setting pre-set criteria (loud, pitch)</td>
</tr>
<tr>
<td>eLOUD</td>
<td>Done</td>
<td>Ready Development required: Data acquisition/collection - integrate LSVT-C with webcam</td>
</tr>
<tr>
<td>LSVT-VT</td>
<td>Done</td>
<td>Prototype: Done Enhancement - Integration of LSVT-C loudness analysis algorithm, animation improvement, engagement/gaming</td>
</tr>
<tr>
<td>Webhub</td>
<td>Done</td>
<td>Need infrastructure for delivery</td>
</tr>
</tbody>
</table>
Changes consistent with those reported in previously published data  Halpern et al, in review
LSVT BIG clip
Comparing Exercise in Parkinson’s Disease —
The Berlin LSVT BIG Study (2010, Movement Disorders)
Georg Ebersbach,* Almut Ebersbach, Daniela Edler, Olaf Kaufhold, Matthias Kusch,
Andreas Kupsch, and Jörg Wissel

UPDRS motor score (blinded rating), mean change from baseline (vertical bars 5 standard deviations). Change between baseline and follow up at week 16 was superior in BIG (interrupted line) compared to WALK (dotted line) and HOME (solid line), P <0.001. ANCOVA did not disclose significant differences between in intermediate and final assessments.
Trademarks: DEFINE

- LSVT
- LSVT COMPANION®
- LSVT BIG™
- LSVT LOUD™
- (US, EU, AU, BR, CA, CH, JP, SG, WO)

Copyrights: DEFINE

- LSVT Training and Certification Workshop Binders and Lectures
- Patient Presentation
- LSVT BIG and LSVT LOUD Marketing Brochures
- LSVT LOUD Patient Assessment and Treatment Pack
- LSVT WEBSITE
LSVT Global, Inc. IP

Patent:
- LSVT® HYBRID
- SPL calibration

Licenses
- University of Arizona, University of Colorado
- All LSVT LOUD and LSVT BIG Certified clinicians
- Healthcare Organizations: HealthSouth, Amedysis

FDA-approval
- LSVT Companion Software
• I WILL MAKE SLIDE WITH DIFFERENCES BETWEEN TRADEMARK, COPYRIGHT AND PATENT
LSVT Global, Inc. Funding

NIH
SBIR R43 DC-010956 (Fox and Ramig)
SBIR R43 DC-010498 (Fox and Ramig)
SBIR R43 DC- (Fox and Ramig)

Davis Phinney Foundation for Parkinson disease

“Organic growth”: revenue from products of the company

“midnight oil”
LSVT Global: Impact in relation to our goal

“Ivory Tower”
Research Lab

Real World
“Clinical Trenches”
Patient Populations

ADD DATA HERE

Bridging Hope
LSVT Global: Impact in relation to our goal

Approximately 30,000 patients with PD have had access to LSVT Treatments

Awareness:
Educate Medical, Professional, and Patient Communities

Accessibility:
Increase access to training and treatment through technology

Change Management:
Getting the rehabilitation professional communities to embrace a new way of delivering treatment
LSVT Global, Inc. Impact in relation to our goal

Increase accessibility to efficacious treatment

Estimate XXX patients receiving LSVT in XX countries

Contracts with healthcare organizations
To a patient......major life impact

“My voice is alive again”
“I can talk to my grandchildren!”
“I feel like my old self”
“I am confident I can communicate!”

“Sharon Quote”
Lessons Learned

Change management
Treatment translation
“Don’t stop believing”
Quotes
• Healthsouth
• Amedysis
• 6,000 speech clinicians
• 1,000 physical therapists, occupational therapists